

# **EXHIBIT B**

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IN THE UNITED STATES DISTRICT COURT  
OF THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC )  
REPAIR SYSTEM PRODUCTS ) Master File No.  
LIABILITY LITIGATION ) 2:12-MD-02327  
-----) MDL 2327

THIS DOCUMENT RELATES TO THE FOLLOWING

CASES IN WAVE 1 OF MDL 200:

MARGARET J. STUBBLEFIELD ) Civil Action No.  
Plaintiff,) 2:12-cv-00842  
vs. )  
ETHICON, INC., ET AL. )  
Defendant. )  
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--- This is the Deposition of VLADIMIR IAKOVLEV, M.D.,  
taken at The Westin Harbour Castle, 1 Harbour Square,  
Toronto, Ontario, on the 21st day of March, 2016.

REPORTED BY: TERRY WOOD, RPR, CSR

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<p>1 Carol Jean Dimock ) v. Ethicon, Inc., et al. ) 2 Civil Action No. 2:12-cv-00401 ) 3 Ana Ruebel ) v. Ethicon, Inc., et al. ) 4 Civil Action No. 2:12-cv-00663 ) 5 Jackie Frye ) v. Ethicon, Inc., et al. ) 6 Civil Action No. 2:12-cv-1004 ) 7 Joan Adams ) v. Ethicon, Inc., et al. ) 8 Civil Action No. 2:12-cv-01203 ) 9 Sharon Boggs, et al. ) v. Ethicon, Inc., et al. ) 10 Civil Action No. 2:12-cv-00368 ) 11 Dina Destefano-Raston, et al. ) v. Ethicon, Inc., et al. ) 12 Civil Action No. 2:12-cv-01299 ) 13 Teresa Georgilakis, et al. ) v. Ethicon, Inc., et al. ) 14 Civil Action No. 2:12-cv-00829 ) 15 Donna Hankins, et al. ) v. Ethicon, Inc., et al. ) 16 Civil Action No. 2:12-cv-01011 ) 17 Nancy Hooper, et al. ) v. Ethicon, Inc., et al. ) 18 Civil Action No. 2:12-cv-00493 ) 19 Krystal Teasley ) v. Ethicon, Inc., et al. ) 20 Civil Action No. 2:12-cv-00500 ) 21 Margaret Stubblefield ) v. Ethicon, Inc., et al. ) 22 Civil Action No. 2:12-cv-00842 ) 23 Cindy Smith ) v. Ethicon, Inc., et al. ) 24 Civil Action No. 2:12-cv-01149 )</p>	<p>1 A P P E A R A N C E S: 2 FOR THE PLAINTIFF AND THE WITNESS: 3 ANDERSON LAW OFFICES, LLC 4 CHRISTOPHER J. ZIMMERMAN, ESQ. 5 1360 West 9th Street, Suite 215 6 Cleveland, Ohio 44113 7 Tel. 216.589.0256 8 Email: christopher@andersonlawoffices.net 9 10 FOR THE DEFENDANT: 11 BUTLER SNOW LLP LLC 12 M. ANDREW SNOWDEN, ESQ. 13 150 3rd Avenue South, Suite 1600 14 Nashville, TN 37201 15 Tel. 615.651.6760 16 Email: andy.snowden@butlersnow.com 17 18 19 20 21 22 23 24</p>

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<p>1 INDEX OF WITNESSES</p> <p>2 WITNESS. PAGE</p> <p>3 VLADIMIR IAKOVLEV, MD, affirmed</p> <p>4 Examination by Mr. Snowden 8</p> <p>5 Examination by Mr. Zimmerman 102</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 --- Upon commencing at 8:10 p.m.</p> <p>2</p> <p>3 (WHEREUPON, the witness was duly affirmed.)</p> <p>4</p> <p>5 VLADIMIR IAKOVLEV, M.D.,</p> <p>6 called as a witness herein,</p> <p>7 having been first duly affirmed,</p> <p>8 was examined and testified as follows:</p> <p>9 EXAMINATION</p> <p>10 BY MR. SNOWDEN:</p> <p>11 Q. Good evening, Dr. Iakovlev.</p> <p>12 A. Good evening.</p> <p>13 Q. We are here to talk about the</p> <p>14 Margaret Stubblefield case; is that your understanding?</p> <p>15 A. I do.</p> <p>16 EXHIBIT NO. 1: Expert report</p> <p>17 BY MR. SNOWDEN:</p> <p>18 Q. I'm handing you what has been</p> <p>19 marked as Stubblefield one. Could you take a look and</p> <p>20 let me know if this is your complete case-specific</p> <p>21 expert report in this case.</p> <p>22 A. Yes, it appears to be complete.</p> <p>23 Q. How much time did you spend</p> <p>24 preparing your opinions in this case?</p>
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<p>1 LIST OF EXHIBITS</p> <p>2 EXHIBIT NO./DESCRIPTION Page</p> <p>3 1 Expert report 8</p> <p>4 2 Flash drive 9</p> <p>5 3 Operative note, 02/04/05 11</p> <p>6 4 Surgical Pathology Final Report, reported 55</p> <p>7 9/28/2009</p> <p>8 5 Operative report 2007/01/04 57</p> <p>9 6 Surgical Pathology Report reported on 82</p> <p>10 2007/01/10</p> <p>11 7 Progress Notes, dated 3/18/05 to 7/8/05 88</p> <p>12 8 Urology Gynecology Operative Report 95</p> <p>13 2009/09/23</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 A. As for other cases, can give you an</p> <p>2 estimate only because I have not completed billing for</p> <p>3 this case. Ballpark would be probably just over 20</p> <p>4 hours, not more than 30 hours.</p> <p>5 Q. Okay. And I've been handed what I</p> <p>6 have now marked as Stubblefield 2. It's a flash drive.</p> <p>7 EXHIBIT NO. 2: Flash drive</p> <p>8 BY MR. SNOWDEN:</p> <p>9 Q. Does this flash drive contain all</p> <p>10 of the case-specific materials you reviewed in this</p> <p>11 case with the exception, of course, of the specimen</p> <p>12 itself?</p> <p>13 A. It should.</p> <p>14 Q. And -- sorry, strike that.</p> <p>15 When I look at your report in this case</p> <p>16 starting on page 11 and then through 13, it looks like</p> <p>17 you've headings in your clinico-pathologic correlation</p> <p>18 for erosion, pain and polypropylene degradation; is</p> <p>19 that right?</p> <p>20 A. That's correct.</p> <p>21 Q. In coming to an opinion regarding</p> <p>22 pain symptomatology, is your opinion necessarily</p> <p>23 dependent on the patient's complaints of pain?</p> <p>24 MR. ZIMMERMAN: Objection. Answer if</p>

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<p>1 you can.</p> <p>2 THE DEPONENT: Well pain has to be</p> <p>3 voiced by the patient, either without examination or</p> <p>4 pain on examination, but patient has to indicate</p> <p>5 somehow that she is feeling pain.</p> <p>6 Otherwise there wouldn't be no -- well,</p> <p>7 I mean, you probably can -- if patient cannot speak,</p> <p>8 you probably see face reaction and emotions indicating</p> <p>9 that somebody is in pain. That's another way of -- but</p> <p>10 still, something is indicated by the patient that she</p> <p>11 feels pain.</p> <p>12 BY MR. SNOWDEN:</p> <p>13 Q. Okay. So implicit in your opinion</p> <p>14 then would be that the -- an assumption that the</p> <p>15 plaintiff's complaints are accurate; is that fair?</p> <p>16 MR. ZIMMERMAN: Objection, form. Go</p> <p>17 ahead, answer it you can.</p> <p>18 THE DEPONENT: I can only see what is in</p> <p>19 the records because I cannot take the history from the</p> <p>20 patient. I'm not urogynecologist, cannot examine to</p> <p>21 identify tenderness in some areas.</p> <p>22 So I can be as accurate as the records</p> <p>23 are.</p> <p>24</p>	<p>1 anterior colporrhaphy with synthetic sling.</p> <p>2 Q. In this case did Ms. Stubblefield</p> <p>3 undergo two procedures both on the anterior vaginal</p> <p>4 wall?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. Do you know where, in</p> <p>7 relation to one another, an anterior colporrhaphy is</p> <p>8 performed versus the synthetic sling that was implanted</p> <p>9 on February 4, 2005?</p> <p>10 A. Well colporrhaphy is along the</p> <p>11 sagittal plane. The sling is in the frontal plane, so</p> <p>12 they are, to a degree, perpendicular to each other.</p> <p>13 Q. Do they overlap?</p> <p>14 A. And colporrhaphy is more higher up,</p> <p>15 proximal where the sling is placed more closer to the</p> <p>16 enterocele.</p> <p>17 Q. Do any portions of those procedures</p> <p>18 overlap?</p> <p>19 A. They may but I would defer this to</p> <p>20 implanting surgeon.</p> <p>21 Q. Okay. If we look in the body of</p> <p>22 the report, beginning -- it says description of</p> <p>23 operation, and if we go -- the fifth line down, it</p> <p>24 reads:</p>
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<p>1 BY MR. SNOWDEN:</p> <p>2 Q. Okay. On page 2 of your expert</p> <p>3 report under urogynecologist history, you have entry</p> <p>4 for hysterectomy. Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. Do you know what type of</p> <p>7 hysterectomy Ms. Stubblefield had?</p> <p>8 A. I don't remember now, but if you</p> <p>9 show me the record I would be able to tell you.</p> <p>10 Q. Does it have any bearing on your</p> <p>11 opinion whether she had a vaginal hysterectomy or</p> <p>12 abdomen hysterectomy?</p> <p>13 A. Not really. It would matter for</p> <p>14 clinicians who is doing clinical differential</p> <p>15 diagnosis. I am not doing clinical differential</p> <p>16 diagnosis. I'm reliant on the clinicians who work up</p> <p>17 the patient and make a decision to excise the mesh.</p> <p>18 EXHIBIT NO. 3: Operative note, 02/04/05</p> <p>19 BY MR. SNOWDEN:</p> <p>20 Q. I'm handing you what's marked as</p> <p>21 Exhibit Stubblefield 3. Do you recognize this to be a</p> <p>22 copy of the implant operative note from February 4,</p> <p>23 2005?</p> <p>24 A. Yes. February 4th, 2005, procedure</p>	<p>1 "A transverse incision was made</p> <p>2 across the body of the cystocele and</p> <p>3 mucosa was retracted laterally."</p> <p>4 Do you see that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. "Sharp and blunt dissection was</p> <p>7 used to isolate and develop the underlying cystocele."</p> <p>8 Do you see that?</p> <p>9 A. I do.</p> <p>10 Q. Would that sort of dissection</p> <p>11 result in scarring on the interior vaginal wall?</p> <p>12 A. After the -- if the mesh was not</p> <p>13 placed and if mucosa would be placed back and sutured,</p> <p>14 there would be some scar. The amount of scarring will</p> <p>15 be much smaller than what we see around the foreign</p> <p>16 object. Because if it heals with first intention, if</p> <p>17 there is no infection or any other complicating</p> <p>18 factors, there will be minimal scar, really thin, which</p> <p>19 will remodel and then some part of it will disappear</p> <p>20 with time.</p> <p>21 But the difference with the wounds which</p> <p>22 do not heal with first intention is presence of the</p> <p>23 foreign objects in the wound, inflammation, or</p> <p>24 infection-related inflammation. All of this will delay</p>

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<p>1 a healing. That's why we call it secondary intention</p> <p>2 when the wound is open and then it heals up with</p> <p>3 granulation tissue and so forth.</p> <p>4 So in this case, scarring which we see</p> <p>5 is actually related to the mesh, because there was</p> <p>6 foreign object in the wound and all that space had to</p> <p>7 be filled with granulation tissue.</p> <p>8 Q. What -- and if we just continue</p> <p>9 reading it says:</p> <p>10 "When this was accomplished, the sling</p> <p>11 was placed at the midurethral area.</p> <p>12 The sling was composed of a piece of</p> <p>13 soft Prolene mesh 6 inches by 1/2 inch."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Is it your understanding that the</p> <p>17 surgeon had to cut a piece of Prolene soft mesh to get</p> <p>18 that shape?</p> <p>19 A. That's my understanding. That's</p> <p>20 what I can see indirectly.</p> <p>21 Q. And do you know how many pores,</p> <p>22 full pores across the width of that mesh there</p> <p>23 would be when it's cut into a half inch strip?</p> <p>24 A. Let's have a look at the gross</p>	<p>1 large pores fitting in the width of the sling.</p> <p>2 Q. The specimen that you've drawn on</p> <p>3 the gross photo on page 15 was that the full width of</p> <p>4 the sling or had portion of it been excised prior to</p> <p>5 this?</p> <p>6 A. My understanding is it's full</p> <p>7 width.</p> <p>8 There's a scale underneath it and the</p> <p>9 scale is in centimeters. So we can see that the width</p> <p>10 is approximately seven, up to 7 millimeters. So this</p> <p>11 would indicate that the sling contracted to 7</p> <p>12 millimeters from half an inch.</p> <p>13 Q. And the basis of your opinion is</p> <p>14 the measurement of the tissue here on page 15?</p> <p>15 A. The comparison of what width of the</p> <p>16 sling is during excision and what is the description,</p> <p>17 unless half inch description in the operative report is</p> <p>18 not accurate. But we all know that all meshes contract</p> <p>19 so there was some degree of contraction.</p> <p>20 Q. In this case are you able to</p> <p>21 quantify the degree of contraction?</p> <p>22 A. Well we can estimate it, so if it</p> <p>23 is half inch, which is approximately 1 or 11</p> <p>24 millimeters I think over -- and if the width is</p>
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<p>1 photograph, page 15 of my report.</p> <p>2 So if you talk about larger pores, not</p> <p>3 the small pores which are in the weave pattern in the</p> <p>4 wool of the larger pores -- was that your question?</p> <p>5 Q. Yeah, so if it's a rectangle, which</p> <p>6 you'd agree six inches by a half inch is a rectangle?</p> <p>7 A. No, I understand that completely.</p> <p>8 So I can show you the larger pores and the smaller</p> <p>9 pores of the mesh which was used.</p> <p>10 Q. Okay. And in the -- I'm talking</p> <p>11 about the half inch dimension so across the short</p> <p>12 dimension of the sling, perpendicular to it, how many</p> <p>13 pores across would that be?</p> <p>14 A. So I can tell you exactly how many</p> <p>15 pores were in the sling. On page 15 there's a gross</p> <p>16 photograph, and you can see clearly the pores, larger</p> <p>17 pores and the smaller pores. Because there are smaller</p> <p>18 pores -- I'll use red marker so we can see.</p> <p>19 So there are smaller pores which are</p> <p>20 formed by complex weave pattern, and then there will be</p> <p>21 larger pores which are formed by this complex weaving</p> <p>22 pattern. And you can actually follow and see how many</p> <p>23 large pores fit in the sling.</p> <p>24 In this case, it was approximately three</p>	<p>1 approximately 7 millimeters -- so the contraction is in</p> <p>2 the ballpark of 35 percent of the width.</p> <p>3 The width could have been reduced due to</p> <p>4 the stretching towards lateral directions during the</p> <p>5 surgery so half inch when it was cut out, but there</p> <p>6 could be some narrowing during the procedure when it</p> <p>7 was placed. And then that narrowing was further</p> <p>8 contracted and the dimension, the width further was</p> <p>9 reduced due to contraction of scar contraction.</p> <p>10 Q. So would you agree that this mesh</p> <p>11 was placed under the midurethra under tension?</p> <p>12 A. I don't know. We have to ask the</p> <p>13 implanting surgeon.</p> <p>14 Q. And if we look at his note, it</p> <p>15 says, "The suspension sutures on the sling were tied</p> <p>16 with appropriate tension." Do you see that? Seven</p> <p>17 lines up from the bottom?</p> <p>18 A. Yes, I do.</p> <p>19 Q. Okay. So at least from this record</p> <p>20 we see that the surgeon is noting tension is being</p> <p>21 placed on this mesh?</p> <p>22 A. That's what the record says.</p> <p>23 Q. Okay. And you haven't reviewed his</p> <p>24 deposition transcript or any treater's deposition</p>

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<p>1 transcript in this case, correct?</p> <p>2 A. No, I have not.</p> <p>3 Q. Okay. Still looking at Exhibit 3</p> <p>4 here, is it your understanding that the suspension</p> <p>5 sutures used in this case were passed suprapubically?</p> <p>6 A. I'm not urogynecologist and I'm not</p> <p>7 doing this procedures, and this procedure is somewhat</p> <p>8 different that I have seen before. So I would have to</p> <p>9 defer all the specifics to the implanting surgeon.</p> <p>10 Q. You are not going to offer any</p> <p>11 opinions in this case about the technique of</p> <p>12 implantation?</p> <p>13 A. No.</p> <p>14 Q. Are you going to offer any opinions</p> <p>15 in this case regarding whether the mesh was flat when</p> <p>16 implanted?</p> <p>17 A. Well this portion of the mesh came</p> <p>18 out flat. It's not folded.</p> <p>19 Q. Do you any opinions in this case</p> <p>20 regarding deformation of mesh?</p> <p>21 A. What curled was the lateral ends,</p> <p>22 not the mid-portion.</p> <p>23 So the middle portion was relatively</p> <p>24 flat, and then the lateral ends were somewhat</p>	<p>1 excision in 2007. So what I see is only what was in</p> <p>2 the remaining mesh or what I can describe.</p> <p>3 Q. Didn't you know -- if you were</p> <p>4 done.</p> <p>5 A. I'm just -- I have to see what was</p> <p>6 your question.</p> <p>7 Q. My question is whether the curling</p> <p>8 that you saw in the mesh was significant to your</p> <p>9 opinion in the case.</p> <p>10 A. Okay. I drifted away.</p> <p>11 MR. ZIMMERMAN: It's a good thing it's</p> <p>12 here. It just might be a different question.</p> <p>13 BY MR. SNOWDEN:</p> <p>14 Q. I don't know whose question you are</p> <p>15 answering.</p> <p>16 A. In this case, the formation of the</p> <p>17 mesh certainly doesn't help, but is not the main</p> <p>18 driving factor. The formation of the mesh is more of a</p> <p>19 larger contributing factor when there is a bulky</p> <p>20 structure or when there are multiple nerves involved in</p> <p>21 the, in the folded or curled mesh or when curling of</p> <p>22 the sling occurs under the urethra and when the area of</p> <p>23 pressure is reduced so it can cut deeper in the tissue.</p> <p>24 So this, these are examples when curling or deformation</p>
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<p>1 distorted, curled or folded longitudinally along the</p> <p>2 length.</p> <p>3 Q. Are you able to say to a reasonable</p> <p>4 degree of medical certainty whether that folding</p> <p>5 occurred in vivo or at the time of placement?</p> <p>6 A. I cannot.</p> <p>7 Q. And what portion -- if you can</p> <p>8 quantify for us, what portion of the mesh that was</p> <p>9 removed had curling?</p> <p>10 A. Lateral ends.</p> <p>11 Q. Okay.</p> <p>12 A. And I described it as lateral ends.</p> <p>13 Q. So if we are talking about the</p> <p>14 whole of the mesh, how much of the mesh -- that's what</p> <p>15 I'm trying to get at -- how much of the mesh was</p> <p>16 curled?</p> <p>17 A. I can only estimate. Won't be</p> <p>18 exact number. Maybe 10 percent, maybe 20, somewhere</p> <p>19 within that ballpark.</p> <p>20 Q. Was the curling that you saw in</p> <p>21 this mesh significant to your opinions in the case?</p> <p>22 A. See, when the mesh was removed</p> <p>23 in 2009 for the specimen I received, this was a removal</p> <p>24 of the remnants of the mesh, because there was previous</p>	<p>1 of folding play greater role in the complications.</p> <p>2 In this specific case it's not as</p> <p>3 permanent, and it's not as significant.</p> <p>4 Q. Okay. You mentioned two answers</p> <p>5 ago or one answer ago about the fact that there was a</p> <p>6 prior explant, so what you received in this case was a</p> <p>7 portion of the mesh that was implanted.</p> <p>8 Are you able -- based on that, are you</p> <p>9 able to tell whether the mesh contracted as we just</p> <p>10 talked about a moment ago? Because I believe -- this a</p> <p>11 long wind up -- I believe when you previously said that</p> <p>12 you could look at this mesh and see how much it had</p> <p>13 contracted because it was the full mesh. Now I think</p> <p>14 you have seen that you've received a remnant and not</p> <p>15 the full mesh. So I'd like to revisit that.</p> <p>16 A. Well, I did know that it is part of</p> <p>17 the mesh.</p> <p>18 Q. Okay.</p> <p>19 A. I was implying actually to the fact</p> <p>20 that there could be more curling in the segment which</p> <p>21 was excised previously. So I do see some curling, but</p> <p>22 it does not mean that that's the only amount of curling</p> <p>23 in the entire sling, because we don't know what was in</p> <p>24 the previous excision.</p>

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<p>1 Q. Are you able to get an accurate</p> <p>2 measurement of the sling as it would have been sitting</p> <p>3 in vivo based on the remnant of the sling you received</p> <p>4 as a gross specimen?</p> <p>5 A. Well the sling was excised -- my</p> <p>6 understanding is the segment -- the sling was excised</p> <p>7 across its length. It's not that there was a strip</p> <p>8 excised along its length to reduce the width of the</p> <p>9 sling. So what we have missing is a length of the</p> <p>10 sling, but the width is preserved.</p> <p>11 Q. Okay. Just so we are all on the</p> <p>12 same page with length and width here, when you say</p> <p>13 width, are you talking about the measurement that was</p> <p>14 initially 6 inches per the operative report?</p> <p>15 A. 6 inches is length.</p> <p>16 Q. And width we are talking about the</p> <p>17 half inch?</p> <p>18 A. Half inch, yes.</p> <p>19 Q. Okay. So which dimension are you</p> <p>20 able to look at the gross specimen and evaluate?</p> <p>21 A. Width. We can evaluate both so --</p> <p>22 but we cannot restore the full length because we have</p> <p>23 missing parts which were removed previously.</p> <p>24 So if we measure this specific portion</p>	<p>1 A. No, I'm just saying that we cannot</p> <p>2 restore the length of the sling in vivo and estimate</p> <p>3 what's difference of the sling which was in vivo</p> <p>4 comparing with the initial length when it was cut out</p> <p>5 from pristine mesh. But we can do approximately, well</p> <p>6 relatively good estimation of what was the width in</p> <p>7 vivo, for the width -- using the photograph on page 15,</p> <p>8 and the widest portion of the mesh is 7 millimeters.</p> <p>9 Q. Okay. During that implantation</p> <p>10 procedure when the sling was placed, was there -- is it</p> <p>11 your understanding that there was additional mesh</p> <p>12 placed?</p> <p>13 A. Yes, there was another patch of</p> <p>14 mesh placed for the anterior colporrhaphy.</p> <p>15 Q. And do you know where that was</p> <p>16 placed in relation to the sling?</p> <p>17 A. Well the anterior colporrhaphy is</p> <p>18 done along the anterior vaginal wall and, as we</p> <p>19 discussed earlier, it's an area somewhat perpendicular</p> <p>20 to the sling placement. I mean, the piece was larger</p> <p>21 piece but its longest dimension would be perpendicular</p> <p>22 to the sling.</p> <p>23 Q. And do you know whether any of the</p> <p>24 portions of mesh removed from Ms. Stubblefield were the</p>
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<p>1 which is excised, we can estimate that the long section</p> <p>2 is about 6 and a half centimeters and then the two</p> <p>3 shorter segments, about a centimeter and then a half so</p> <p>4 seven and a half, eight, eight centimeters. So we are</p> <p>5 missing about four centimeters of six inches. Am I</p> <p>6 right?</p> <p>7 Approximately, roughly because in inches</p> <p>8 just over two centimeters, 22 millimeters or so.</p> <p>9 That would be an estimate. Again, we</p> <p>10 cannot restore length because we don't know exactly how</p> <p>11 much of it was removed unless we -- okay. If we go to</p> <p>12 pathology description in 2007, "received 4 small pieces</p> <p>13 of pink-red tissue and mesh with cautery artifact.</p> <p>14 Piece 1 measures 3," largest dimension is 3, and then</p> <p>15 largest dimension is 1.3 and then 1.7. And piece</p> <p>16 number 4 largest dimension is 4.5. It's not clearly</p> <p>17 what's the relationship between these pieces, but it</p> <p>18 could be as much of, as 7 centimeters of the mesh</p> <p>19 excised at that time or even more, up to 10</p> <p>20 centimeters. So in this case full length could be 18,</p> <p>21 almost 18, 19 centimeters which is way beyond 6 inches.</p> <p>22 Q. So if I understand your testimony,</p> <p>23 are you saying we are not sure the size of the sling</p> <p>24 when it was initially implanted?</p>	<p>1 anterior -- strike that.</p> <p>2 Do you know whether any of the portions</p> <p>3 of the mesh removed from Ms. Stubblefield were portions</p> <p>4 of the Gynemesh PS used for the cystocele repair?</p> <p>5 A. Hmm, there were smaller pieces</p> <p>6 removed. So the long piece is consistent with the</p> <p>7 sling and the location where it was described -- what</p> <p>8 was the excision report?</p> <p>9 MR. ZIMMERMAN: That's implant.</p> <p>10 THE DEPONENT: Sorry. Excision report</p> <p>11 is here or my summary of the excision.</p> <p>12 So they excised mesh remnants from the</p> <p>13 retropubic space, and they excised remnants of the</p> <p>14 vaginal wall mesh.</p> <p>15 So some portions are actually from the</p> <p>16 vaginal wall mesh in 2009, and we can see by gross</p> <p>17 pictures that there on page 14, you can see that there</p> <p>18 is one long piece, which is more consistent with sling,</p> <p>19 and then there are smaller portions, two smaller or</p> <p>20 three smaller portions. But if you want me to go into</p> <p>21 the details of that excision, I would ask for the</p> <p>22 excision operative report.</p> <p>23 BY MR. SNOWDEN:</p> <p>24 Q. We going to get to that, but just</p>

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<p>1 not yet.</p> <p>2 I ask, in this case you received it</p> <p>3 looks like several hundreds of pages of medical records</p> <p>4 for Ms. Stubblefield. Then those are contained on your</p> <p>5 flash drive.</p> <p>6 Did you review all of those records in</p> <p>7 this case?</p> <p>8 A. I review all records in all cases.</p> <p>9 Screened them through, identifying what is relevant.</p> <p>10 Q. Okay. And when reviewing -- so did</p> <p>11 you request all of the medical records in this case?</p> <p>12 A. I ask for all available records in</p> <p>13 all cases. I mean for me, the main -- the key records</p> <p>14 are implantation, and then reasons for explantation,</p> <p>15 and explantation. These are three key records for me.</p> <p>16 This is the minimum I need. But in most cases I</p> <p>17 receive more than that. And I go through them.</p> <p>18 I mean, of course, if you have more</p> <p>19 records you can extract more information, and</p> <p>20 especially there are several excisions, you can see the</p> <p>21 reasons for each excision and you can see how much of</p> <p>22 that was removed at each excision.</p> <p>23</p> <p>24 Q. So in this case -- okay. Strike</p>	<p>1 and sometimes they are not in chronological order.</p> <p>2 Sometimes I end up first going through records in the</p> <p>3 middle and then jump to the front, then there are</p> <p>4 duplicate entries. It's all over the place.</p> <p>5 I start including from page 1. I don't</p> <p>6 want to come back and re-review the records, so I</p> <p>7 include what I think is relevant, what I see is</p> <p>8 relevant, and then continue including it. And I don't</p> <p>9 know how much of that relevant information I will find</p> <p>10 in the pages which are ahead of me.</p> <p>11 So I don't have specific target of how</p> <p>12 many pages or how many records. I need to just go</p> <p>13 through them and see if something is relevant, I</p> <p>14 include it and then continue on.</p> <p>15 It also depends on the quality of PDF</p> <p>16 files. If I can copy information, I copy it. If I</p> <p>17 cannot copy, I have to provide my own summary, reading</p> <p>18 through it. Sometimes I cannot read it's so poor</p> <p>19 quality or handwriting.</p> <p>20 Q. In this case you received a gross</p> <p>21 specimen, a tissue; is that correct?</p> <p>22 A. That is correct.</p> <p>23 Q. And it was in formalin?</p> <p>24 A. That is correct.</p>
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<p>1 that.</p> <p>2 What's the significance of the summary</p> <p>3 that you've included in your report for</p> <p>4 Ms. Stubblefield? And that runs from page 1 through 9.</p> <p>5 A. So as I indicated in other cases, I</p> <p>6 do not do comprehensive differential diagnosis or</p> <p>7 comprehensive clinical differential diagnosis. What I</p> <p>8 do is provide a background of the specimen I receive.</p> <p>9 The implementation, the development of symptoms, the</p> <p>10 work up of the clinicians when they go through their</p> <p>11 clinical differential diagnosis and the decision to</p> <p>12 excise the mesh, so it provides a context for the</p> <p>13 specimen I examine. And the indication that the</p> <p>14 differential diagnosis was performed by the clinicians</p> <p>15 and the decision to excise the mesh was final decision</p> <p>16 after the clinical workup.</p> <p>17 Q. And how did you determine in this</p> <p>18 case to include the eight or so -- or nine page -- let</p> <p>19 me get this right -- from page 1 to page 9 in this</p> <p>20 summary versus other cases where you have included one</p> <p>21 page of the key records you've just described, implant,</p> <p>22 reasons for explant, and the explant?</p> <p>23 A. As I said, when I go through the</p> <p>24 records I don't know what I'm going to find further on</p>	<p>1 Q. All right. It was from the 2009</p> <p>2 explant procedure, correct?</p> <p>3 A. Correct, September 23, 2009.</p> <p>4 Q. Did you process this specimen in</p> <p>5 the standard tissue process, using the standard tissue</p> <p>6 processing protocol you've used in all the cases?</p> <p>7 A. The processing methodology is the</p> <p>8 same for all laboratories. All diagnostic laboratories</p> <p>9 use the same -- I mean, all histological labs use the</p> <p>10 same protocols, and they use the same machines and the</p> <p>11 same reagents. They are bought from suppliers and the</p> <p>12 machines are programmed and adjusted by the</p> <p>13 manufacturers.</p> <p>14 Q. Okay. Is it your understanding</p> <p>15 that during the implant Prolene sutures were used to</p> <p>16 suspend the sling into place?</p> <p>17 A. I don't see -- oh, I see one, at</p> <p>18 least one. There was a Prolene suture tied to the</p> <p>19 sling before placement.</p> <p>20 Q. Okay. And then -- sorry, go ahead.</p> <p>21 A. They were pulled. I don't see then</p> <p>22 description of how they were trimmed or cut completely,</p> <p>23 so it's not clear if they were left in body after that.</p> <p>24 Q. Okay. On figure MS1 on page 14 of</p>

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<p>1 your report -- one back -- the suture you see there, is</p> <p>2 that consistent with Prolene?</p> <p>3 A. Yes, but that suture is for</p> <p>4 excision, not for placement as far as -- if we --</p> <p>5 again, if you give me the excision operative report, we</p> <p>6 can read what was used.</p> <p>7 Q. Okay. Well, before we get there,</p> <p>8 let's look at -- we are still looking at the implant</p> <p>9 operative report. It mentions that the cystocele</p> <p>10 repair was then covered with a piece of the same mesh</p> <p>11 and sutured into place laterally using 3-0 Ethibond.</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. Did you find any Ethibond in your</p> <p>15 specimen?</p> <p>16 A. To my recollection, no.</p> <p>17 Q. Okay.</p> <p>18 A. Because if I see it, I usually</p> <p>19 include description and pictures.</p> <p>20 Q. And the suture found on page 14 of</p> <p>21 your report, did you submit any of that suture for</p> <p>22 processing?</p> <p>23 A. The part which is in smaller pieces</p> <p>24 in -- is in the sections.</p>	<p>1 were talking about contraction of the tissue. So this</p> <p>2 is the edge of the tissue, or of the specimen.</p> <p>3 Q. You have drawn a red line.</p> <p>4 A. Yes. And then if we follow scar,</p> <p>5 at least in this pore we can see the retraction of the</p> <p>6 scar plate or scar tissue retraction into the mesh. So</p> <p>7 that indentation is due to scar contraction. And it</p> <p>8 cannot be due to fixation of the tissue because we see</p> <p>9 the edge which is a different shape.</p> <p>10 So that fat was pulled into the mesh</p> <p>11 pore because scar in this area.</p> <p>12 Q. Which you have circled with red?</p> <p>13 A. Yes, was contracting. So the</p> <p>14 contraction was pulling all tissue in, and that</p> <p>15 specific pore shows the mechanism how normal fat tissue</p> <p>16 becomes incorporated into the pores. It's because of</p> <p>17 the contraction of the scar within the mesh.</p> <p>18 Q. And for the record, you have drawn</p> <p>19 next to the word "fat", you have drawn an arrow</p> <p>20 pointing where you say the mesh -- the tissue has</p> <p>21 contracted pulling the fat into the pore space.</p> <p>22 A. So in this case we can see the</p> <p>23 extent of contraction at least in that specific pore,</p> <p>24 because we see the interface with normal tissue.</p>
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<p>1 Q. Okay. Do you have a figure that</p> <p>2 shows that suture in the section?</p> <p>3 A. Because it is thicker, much thicker</p> <p>4 than mesh fibers, it may or may not stay on the</p> <p>5 sections. Because usually what happens with thicker</p> <p>6 fibers, they pop out completely. So they just don't</p> <p>7 stay in the tissue. Because that Prolene suture is at</p> <p>8 least three times thicker than the mesh fibers. It's</p> <p>9 really firm when it's so thick and does not stay in the</p> <p>10 tissue.</p> <p>11 Q. All right. Let's start going</p> <p>12 through your pictures. Figure MS3.</p> <p>13 A. Which page?</p> <p>14 Q. Page 16.</p> <p>15 A. Yes.</p> <p>16 Q. What significance, if any, do you</p> <p>17 attribute to this picture?</p> <p>18 A. So this specific part of the mesh</p> <p>19 has folding and the scar tissue grew into the folds and</p> <p>20 between the folds. So the mesh became incorporated in</p> <p>21 this folded configuration. And we can see that most of</p> <p>22 the tissue around the mesh is scar tissue. There's a</p> <p>23 ring of normal fat tissue outside of the scar plate.</p> <p>24 Now what is interesting, remember we</p>	<p>1 Q. Okay. Can you look at this picture</p> <p>2 and tell us whether this, the pathology here is causing</p> <p>3 any symptoms in Ms. Stubblefield?</p> <p>4 A. We cannot take one picture or</p> <p>5 single out one feature and say that that's what is</p> <p>6 causing all the symptoms. It's not like that. You</p> <p>7 have to consider the entire mesh together with all the</p> <p>8 tissue changes which are triggered by the mesh as one</p> <p>9 lesion which is causing the symptoms.</p> <p>10 Q. Figure MS4 on page 17, what</p> <p>11 significance, if any, do you attribute to this photo?</p> <p>12 A. And I will answer all questions I'm</p> <p>13 asked at trial for MS3 and I will expand that summary I</p> <p>14 just gave, so I would not be limited to a -- the</p> <p>15 summary which we just discussed regarding that</p> <p>16 photograph.</p> <p>17 MS4 on page 17 shows another area of</p> <p>18 curled mesh. Now interestingly, this is embedded in a</p> <p>19 way where we can see more fat within the fold. So I</p> <p>20 think it's a cutting through cup-like shape of the</p> <p>21 mesh. So when we cut through this cup, the fat tissue,</p> <p>22 which is inside, became in the middle. So this would</p> <p>23 be -- this type of shape of the mesh, that's how we see</p> <p>24 fat tissue within or inside the mesh fold.</p>

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<p>1 Q. So you have drawn sort of oval</p> <p>2 shape on page 17.</p> <p>3 A. It's somewhat similar to a spoon.</p> <p>4 That's the likely scenario how this appearance was</p> <p>5 generated in histological section.</p> <p>6 Q. How do you rule out tissue</p> <p>7 processing as a cause of that?</p> <p>8 A. Well, tissue processing cannot</p> <p>9 cause scarring. Tissue processing cannot cause fat to</p> <p>10 appear in this areas. I mean it's just present there.</p> <p>11 All of these tissues together, fats, scar and the mesh</p> <p>12 itself, are subject to all changes during tissue</p> <p>13 processing. And you can see that that shape is not</p> <p>14 flat mesh. It's either curled one layer, which is not</p> <p>15 as likely, or cup-shape mesh section at the edges of</p> <p>16 this cup or it's like a spoon-like shape.</p> <p>17 Q. Are there any pores in this picture</p> <p>18 with fat tissue within them?</p> <p>19 A. Yes, there are.</p> <p>20 Q. How many?</p> <p>21 A. Several, at least three. So in</p> <p>22 this specific case, the fat was retracted and slowly</p> <p>23 pushed its way into the pores. It's the same mechanism</p> <p>24 as in the previous picture. The mesh is placed in the</p>	<p>1 will use green marker which has sectioned parallel to</p> <p>2 their access or parallel to the plane of the mesh. So</p> <p>3 all of these fibers are sectioned parallel.</p> <p>4 So this pattern is only possible when we</p> <p>5 section parallel to the mesh.</p> <p>6 Q. Okay.</p> <p>7 A. Then we section the mesh fibers</p> <p>8 along their long axis or along their length.</p> <p>9 Q. And what was your reason for</p> <p>10 including this picture in your report?</p> <p>11 A. Here you can see again the same</p> <p>12 phenomenon, scar plating, bridging fibrosis and then in</p> <p>13 some areas fat is being pulled into the pores.</p> <p>14 Q. Okay. So in the areas here where</p> <p>15 fat is in the pores, is there any -- strike that.</p> <p>16 The fat that you see in the pore spaces</p> <p>17 here, is it your testimony that was all pulled into the</p> <p>18 pore as a result of contraction?</p> <p>19 A. I think that's the only viable</p> <p>20 mechanism to, and you can see it in other images that</p> <p>21 that's what is happening.</p> <p>22 Q. Is there anything else abnormal in</p> <p>23 figure MS5?</p> <p>24 A. Well, I can talk for a long time</p>
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<p>1 body, all the spaces within the mesh are filled with</p> <p>2 blood and then there is granulation tissue and then</p> <p>3 when it matures, it contracts. And when it contracts</p> <p>4 it starts pulling fat tissue through the pores into the</p> <p>5 mesh. And in this case we have a tangential view of</p> <p>6 this process in page MS4 -- sorry, on page 17, picture</p> <p>7 MS4.</p> <p>8 Q. And that process you just</p> <p>9 described, does that occur with any mesh?</p> <p>10 A. You mean contraction of scar tissue</p> <p>11 and pulling of normal tissue into the pores?</p> <p>12 Q. That the blood is there and then</p> <p>13 that brings the healing that you just described.</p> <p>14 A. Yes. It's a nonspecific mechanism</p> <p>15 for healing. All empty spaces in the body first are</p> <p>16 filled with body fluids. Most commonly it's blood clot</p> <p>17 and then that blood clot is being replaced by</p> <p>18 granulation tissue or that's what we call organization,</p> <p>19 organizing blood clot.</p> <p>20 Q. MS5 on page 18, what do we see here</p> <p>21 in this picture?</p> <p>22 A. So this is a flat portion of the</p> <p>23 mesh. And it's embedded parallel to the plane of</p> <p>24 sectioning. You can see several mesh fibers, and I</p>	<p>1 about this image. I will answer all questions I'm</p> <p>2 asked at the trial and expand this summary.</p> <p>3 The main abnormality here is presence of</p> <p>4 the foreign body scar encapsulation, bridging fibrosis.</p> <p>5 We can see some of the foreign-body type reaction from</p> <p>6 this power. And we can see or I can demonstrate the</p> <p>7 difference between scar plate and surrounding normal</p> <p>8 fat tissue.</p> <p>9 Q. Are you able to tie any</p> <p>10 complications to the figure MS5?</p> <p>11 A. I'm not tying complications to</p> <p>12 specific or one single picture in any of these cases.</p> <p>13 What I'm doing, I'm describing all the changes which</p> <p>14 are occurring at the same time in relation to the mesh,</p> <p>15 all tissue changes; they work together. I mean there</p> <p>16 will be contribution, more contribution of one factor</p> <p>17 comparing to the other, but they will all be present at</p> <p>18 the same time. And we can observe them at the same</p> <p>19 time in the same specimen.</p> <p>20 Q. Did you consult a neuropathologist</p> <p>21 in this case?</p> <p>22 A. For this case, as for all other</p> <p>23 cases, I neither consulted nor needed to consult a</p> <p>24 neuropathologist to arrive to my opinions.</p>

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<p>1           Neuropathologists examine brain and</p> <p>2           spinal cord lesions and some larger peripheral nerves</p> <p>3           for neurodegenerative diseases. In this case, it's not</p> <p>4           a brain tissue. It's vaginal tissue. It's a foreign</p> <p>5           body implanted for urogynecological reasons. And the</p> <p>6           nerves I observed did not show degeneration or</p> <p>7           degenerative disease.</p> <p>8           The location was abnormal. They were</p> <p>9           present in the mesh, and they were present in the scar</p> <p>10          tissue. That was abnormal, but the nerves themselves</p> <p>11          did not show much pathology.</p> <p>12          Q. Okay. What pathology did they</p> <p>13          show, if they didn't show much?</p> <p>14          A. So the main abnormality here on</p> <p>15          page 20 is presence of the nerves inside the mesh,</p> <p>16          embedded in the scar tissue which fills the mesh.</p> <p>17          That's the main abnormality. From this low power I</p> <p>18          cannot assess for degeneration, but it is not apparent</p> <p>19          from this view.</p> <p>20          Q. Okay. Figure MS6 and MS7, are</p> <p>21          those similar portions of the tissue? One is in H&amp;E</p> <p>22          and one is a -- is an s100; is that right?</p> <p>23          A. It's possible. Likely.</p> <p>24          Q. And if we look at where the mesh</p>	<p>1           on H&amp;E picture. It's not microscopic slide where I can</p> <p>2           zoom in and zoom out.</p> <p>3                        So my accuracy may be somewhat</p> <p>4           limited.</p> <p>5                        Q. Okay. So you have drawn green</p> <p>6           circles on the figure MS6.</p> <p>7                        A. I think that's pretty accurate</p> <p>8           comparing with s100.</p> <p>9                        Q. Okay.</p> <p>10                      A. I didn't look at this, so I just</p> <p>11           drew it.</p> <p>12                      Q. So the structures where the arrows</p> <p>13           hit on figure MS6 are sort of below where you've</p> <p>14           circled the nerves?</p> <p>15                      A. Well, I'm pointing with the arrows</p> <p>16           not specific point, but the location of the nerves.</p> <p>17           And you can see there are four nerves here.</p> <p>18                      Q. Okay.</p> <p>19                      A. And the arrows are just pointing in</p> <p>20           general direction of the nerves.</p> <p>21                      Q. Okay. Did you do any axonal</p> <p>22           staining in this case?</p> <p>23                      A. I did not need to do axonal</p> <p>24           staining, and I did not do it.</p>
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<p>1           spaces are, they sort of line up together moving from</p> <p>2           MS6 to MS7; is that right?</p> <p>3                      A. That is correct.</p> <p>4                      Q. Okay. In this case you have two</p> <p>5           pictures depicting nerves; is that right?</p> <p>6                      A. Yes, there are two images.</p> <p>7                      Q. And I think we've just established</p> <p>8           they are from the same area?</p> <p>9                      A. Yes, they are likely from the same</p> <p>10          area.</p> <p>11                      Q. They are essentially like two</p> <p>12          slices of baloney on top of each other?</p> <p>13                      A. Yes, if you can put it this way.</p> <p>14                      Q. I was trying to think of a way.</p> <p>15          Anyway --</p> <p>16                      A. I used salami slices.</p> <p>17                      Q. Salami, baloney, whatever.</p> <p>18                      So if we look at MS6, which portion --</p> <p>19          and you have arrows pointing in MS6, you have the word</p> <p>20          on lower panel the word "nerves" and then you have two</p> <p>21          arrows. Could you circle on the upper picture where --</p> <p>22          in green pen which portion of that specimen has nerves?</p> <p>23          Just circle the nerves for me.</p> <p>24                      A. Again, this will be estimate based</p>	<p>1                      Q. Did you analyze the specimen to</p> <p>2           look for axons under -- using s100 or H&amp;E?</p> <p>3                      A. Sorry, it says --</p> <p>4                      --- DISCUSSION OFF THE RECORD ---</p> <p>5                      BY MR. SNOWDEN:</p> <p>6                      Q. Did you analyze the specimen to</p> <p>7           look for axons using s100 or H&amp;E?</p> <p>8                      A. I don't need to examine axons.</p> <p>9                      Q. Did you do it?</p> <p>10                     A. That's why I did not do it, because</p> <p>11          I did not need to.</p> <p>12                      Q. Did you identify any nerve</p> <p>13          receptors in this case?</p> <p>14                      A. The answer will be the same. I did</p> <p>15          not need to identify nerve receptors.</p> <p>16                      Q. Did you count the nerve density in</p> <p>17          Ms. Stubblefield's specimen?</p> <p>18                      A. If you received synoptic report, I</p> <p>19          did. If you did not, then I wouldn't. I think I saw</p> <p>20          something about ...</p> <p>21                      Q. No synoptic report received is what</p> <p>22          you saw.</p> <p>23                      MR. ZIMMERMAN: Well, that's at least a</p> <p>24          clear answer.</p>

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<p>1 BY MR. SNOWDEN:</p> <p>2 Q. So I will represent to you we did</p> <p>3 not receive a synoptic report in this case.</p> <p>4 Would you agree that you didn't see any</p> <p>5 traumatic neuromas in this case?</p> <p>6 A. I do. I do agree. Or traumatic</p> <p>7 neuroma-type of lesions within the mesh.</p> <p>8 Q. Okay. None of those either?</p> <p>9 A. None of those.</p> <p>10 Q. The nerves found in MS6, are you</p> <p>11 able to tell on the H&amp;E whether those are pain</p> <p>12 mediating nerves?</p> <p>13 A. Well, all peripheral nerves or most</p> <p>14 of them are mixed, so they contain motor fibers and</p> <p>15 sensory fibers afferent and efferent.</p> <p>16 Q. Are you able to look at the s100 or</p> <p>17 H&amp;E of these nerves and determine that?</p> <p>18 A. It's just general neuroanatomy that</p> <p>19 most of the nerves are mixed.</p> <p>20 Q. Do you know where -- strike that.</p> <p>21 Do you know what these nerves are innervating?</p> <p>22 A. Tissue within the anterior vaginal</p> <p>23 wall and the bladder in that area.</p> <p>24 Q. Do you know how far their targets</p>	<p>1 getting close to the vaginal mucosa, they will be</p> <p>2 somatic or likelihood of them being somatic will be</p> <p>3 higher. If you are getting deeper in the bladder wall,</p> <p>4 there won't be any somatic nerves. All of them will be</p> <p>5 autonomic.</p> <p>6 Q. Do you know how close this slide is</p> <p>7 from the bladder wall or the mucosa, vaginal mucosa?</p> <p>8 A. Well see, I did not see any</p> <p>9 portions of the bladder wall in this specimen.</p> <p>10 Q. Do you see any mucosa -- vaginal</p> <p>11 mucosa in this specimen?</p> <p>12 A. No.</p> <p>13 Q. Is it fair to say you don't have a</p> <p>14 marker above or below, and above meaning bladder and</p> <p>15 below meaning vaginal mucosa, to orient where the MS7</p> <p>16 came from?</p> <p>17 A. No. Also some pieces also came</p> <p>18 from the retropubic space.</p> <p>19 Q. And what would be the significance</p> <p>20 if the portion was from the retropubic space?</p> <p>21 A. See, if it's retropubic space,</p> <p>22 likelihood of those being somatic is higher than</p> <p>23 autonomic, because autonomic nerves running from below</p> <p>24 to the bladder. The innervation pattern is from</p>
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<p>1 are away from this section?</p> <p>2 A. Well, they will have targets along</p> <p>3 the course of the nerve, so they will be branching on</p> <p>4 its way. So there will be targets close by and then</p> <p>5 nerve continues on and the targets will be further</p> <p>6 down. So some of the targets are close by. Especially</p> <p>7 considering these are not large nerves, so they will</p> <p>8 branch out in relative proximity.</p> <p>9 Q. If you look at the s100 and MS7, it</p> <p>10 looks like in the middle of the picture there are sort</p> <p>11 of two larger s100 positive staining structures. Do</p> <p>12 you see what I'm talking about?</p> <p>13 A. I do.</p> <p>14 Q. Just below that, is that a vessel?</p> <p>15 A. Yes, there are vessels there. So</p> <p>16 it's normal anywhere in the body to form neurovascular</p> <p>17 bundles. There is usually one nerve and arteries or</p> <p>18 arterials and veins. It's how they run parallel to</p> <p>19 each other. Certain point they deviate and they run</p> <p>20 alone.</p> <p>21 Q. Are you able to tell whether these</p> <p>22 are autonomic nerves?</p> <p>23 A. No, they can be either motor or</p> <p>24 autonomic depending on their location. If we are</p>	<p>1 lateral and below and going into the bladder. If you</p> <p>2 are going above the bladder, all autonomic or most of</p> <p>3 the autonomic innervation is already ended in the</p> <p>4 bladder.</p> <p>5 Q. The nerves or the s100 positive</p> <p>6 staining structures in the top left of the picture,</p> <p>7 are there vessels around those as well?</p> <p>8 A. Yes. I think it might be the same</p> <p>9 neurovascular bundle just diving in and diving out.</p> <p>10 There might be two nerves or it might be -- well, most</p> <p>11 likely there are two nerves running parallel.</p> <p>12 Q. In either of these figures, MS6 or</p> <p>13 MS7, is there any inflammation infiltrating the nerves?</p> <p>14 A. I cannot appreciate it from this</p> <p>15 power. I don't see it from this power, but it does not</p> <p>16 mean that it's not there.</p> <p>17 Q. Do you recall making that finding</p> <p>18 one way or the other when you were looking at these</p> <p>19 under microscope?</p> <p>20 A. No. Usually I don't see</p> <p>21 inflammation in the nerves. As I said, the main</p> <p>22 abnormality in the nerves is their location, not</p> <p>23 something within the nerves. Sometimes I see</p> <p>24 degenerative of the nerves and sometimes I see there</p>

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<p style="text-align: right;">Page 46</p> <p>1 is distortion and separation within the scar tissue.</p> <p>2 Q. MS8, if you could turn there, what</p> <p>3 does this show?</p> <p>4 A. This is an H&amp;E slide. It shows</p> <p>5 several mesh fibers, a cluster of mesh fibers. And</p> <p>6 that cluster is on the left and close to the lower</p> <p>7 border, and then the upper right corner is filled with</p> <p>8 scar tissue and there is a cluster of chronic</p> <p>9 lymphocytic inflammation in the area.</p> <p>10 Q. What significance, if any, would</p> <p>11 you attribute to this finding?</p> <p>12 A. It shows increased inflammation.</p> <p>13 This would be abnormal to have in normal vaginal</p> <p>14 tissue. Increases burden of inflammation within the</p> <p>15 mesh.</p> <p>16 Q. Overall in Ms. Stubblefield's</p> <p>17 specimen, how would you rate the chronic inflammatory</p> <p>18 infiltrate?</p> <p>19 A. I cannot grade it using just one</p> <p>20 spot. How I do it, I use objective times four and I</p> <p>21 count number of fossa like this.</p> <p>22 Q. Did you do that in this case?</p> <p>23 A. If I did synoptic report, I did but</p> <p>24 we determined ...</p>	<p style="text-align: right;">Page 48</p> <p>1 A. So I will not single out one</p> <p>2 specimen's pathological feature or histological feature.</p> <p>3 They all occur in the same specimen together. Some of</p> <p>4 them have greater roles; some of them have lesser role.</p> <p>5 But overall we cannot separate them, because they are</p> <p>6 all incurring in response to mesh. And when they all</p> <p>7 occur together, they cause symptoms.</p> <p>8 Q. Figure MS9, what are you showing</p> <p>9 here?</p> <p>10 A. This is a different type of</p> <p>11 inflammation. This is, again, an H&amp;E stain slide with</p> <p>12 cluster of mesh fibers. And in the middle of this</p> <p>13 image, there is foreign-body type inflammation reacting</p> <p>14 to the mesh. And the corners, upper right corner and</p> <p>15 the lower left corner is filled with scar tissue. So</p> <p>16 that scar tissue is part of the scar plate.</p> <p>17 Q. Okay. And -- sorry, are you</p> <p>18 finished?</p> <p>19 A. And you can also see degradation</p> <p>20 bark in some of the fibers.</p> <p>21 Q. In the upper right portion of the</p> <p>22 picture, the tissue closest to or abutting the mesh</p> <p>23 fiber, are there any giant cells there?</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Okay.</p> <p>2 A. That why I did not do it.</p> <p>3 Q. Okay. So in some cases you have</p> <p>4 done that, but not in this one?</p> <p>5 A. Well, I do not require those type</p> <p>6 of measurements to formulate my opinions. As I said,</p> <p>7 any degree of inflammation is abnormal -- well, that</p> <p>8 degree of inflammation is abnormal, and I'm not basing</p> <p>9 it on the number of clusters of these chronic</p> <p>10 inflammatory cells but their amount, their clustering.</p> <p>11 So this is an abnormal finding already without grading.</p> <p>12 Q. If you see one cluster like this in</p> <p>13 MS8, is that significant to your opinion?</p> <p>14 A. Everything is significant to my</p> <p>15 opinion. All of this is abnormal. I'm describing the</p> <p>16 abnormalities. So as in any pathological specimen,</p> <p>17 when we examine, we describe what is abnormal, what is</p> <p>18 different with the tissue which is expected to be seen</p> <p>19 there or with our knowledge of normal histology in the</p> <p>20 area.</p> <p>21 Q. What clinical symptoms do you</p> <p>22 attribute to the presence of chronic inflammation in</p> <p>23 this specimen? And I don't mean just this picture. I</p> <p>24 mean overall in Ms. Stubblefield's specimen.</p>	<p style="text-align: right;">Page 49</p> <p>1 Q. And in the space, the -- well, the</p> <p>2 fiber is still present there, correct?</p> <p>3 A. That is correct.</p> <p>4 Q. And there's degradation bark along</p> <p>5 that area where there are no giant cells; is that</p> <p>6 correct?</p> <p>7 A. That is correct.</p> <p>8 Q. Are there giant cells on the lower</p> <p>9 left portion of the tissue in the lower left corner</p> <p>10 where it's abutting the tissue -- the tissue abuts the</p> <p>11 mesh?</p> <p>12 A. Do you mean other macrophages as</p> <p>13 part of foreign body reaction? Giant cells --</p> <p>14 macrophages don't always form giant cells. So foreign</p> <p>15 bodies formed by macrophages, but they are not always</p> <p>16 giant cells.</p> <p>17 I see few cells, few macrophages but</p> <p>18 they amount is not the same as what is occurring in the</p> <p>19 middle of the image.</p> <p>20 Q. Okay. Is the presence of these</p> <p>21 foreign body giant cells in the middle of this figure,</p> <p>22 significant to your opinion?</p> <p>23 A. As I said, everything is</p> <p>24 significant. Everything is abnormal. Presence of</p>

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<p style="text-align: right;">Page 50</p> <p>1 foreign body reaction of any degree is abnormal in the  2 tissue. Normally there is no foreign body reaction in  3 tissues. And this type of inflammation contributes to  4 all the changes which are triggered by the mesh  5 together with a chronic inflammation we discussed  6 earlier, scar plate formation and other features we  7 discussed earlier. All of that works together.  8 Q. And in Ms. Stubblefield's case,  9 does the presence of foreign body inflammation indicate  10 that the mesh is not biocompatible?  11 A. It depends on how we determine or  12 how we use the term "biocompatible." If we want to use  13 the term "biocompatibility" to describe a device or a  14 material which would be completely inert, then I would  15 say the mesh is not inert. The mesh triggers foreign  16 body reaction.  17 Q. Are you going to be offering an  18 opinion in this case regarding whether  19 Ms. Stubblefield's mesh is biocompatible?  20 A. Hmm, I don't think I used that word  21 in either my general report or in this case-specific  22 report.  23 Q. Okay. So is that a no?  24 A. Just don't describe it. What I can</p>	<p style="text-align: right;">Page 52</p> <p>1 actually formation of giant cells. So when the  2 macrophages cannot destroy an object, they merge  3 together to form these larger cells or giant cells,  4 multinucleated cells in an attempt to phagocytose or  5 swallow the body, the foreign body.  6 The degree of foreign body reaction here  7 is greater than what we saw in the previous image.  8 There is also scarring or bridging fibrosis just outside  9 of the mesh fibers and in between the mesh fibers. So  10 all of the tissue which is in this image is abnormal.  11 There is a presence of foreign body. There's scar  12 bridging. There is scar plate formation. And then  13 there is foreign-body type reaction with a number of  14 larger giant cells.  15 Q. The foreign-body type inflammation  16 that you show in MS9 and MS10 is that representative of  17 a degree of foreign body inflammation throughout the  18 specimen?  19 A. I'm not sure what you mean. I  20 don't understand the question.  21 Q. So --  22 A. It's representative of the area I  23 took photograph. It's exact copy what was in there.  24 Q. Right. Is it representative of the</p>
<p style="text-align: right;">Page 51</p> <p>1 say is that it's not inert.  2 Q. And will you be telling the ladies  3 and gentleman of the jury about the principles of  4 biocompatibility and whether Ms. Stubblefield's mesh  5 was biocompatible?  6 A. Again, I did not provide any  7 opinions regarding biocompatibility in either my  8 general report or case-specific report. If I am asked  9 regarding this type of questioning, I think the best  10 wording would be as inertness, because biocompatible or  11 biocompatibility terminology can be used as long as we  12 agree what it means in -- for different people, it may  13 mean different. When we see inert and not inert, that  14 implies that either there is reaction against it or  15 there is no reaction. And in this case we do know that  16 there is reaction. So it's not inert. It triggers a  17 reaction, foreign-body response, foreign-body type  18 inflammatory reaction, it triggers scar encapsulation.  19 All of that is a response to an object, therefore, it's  20 not inert.  21 Q. Figure MS10, if you can turn your  22 attention there, what does this picture show?  23 A. So now this image shows another  24 area of an H&amp;E stain slide, and this area shows</p>	<p style="text-align: right;">Page 53</p> <p>1 foreign body reaction found throughout the entire  2 specimen?  3 A. I'm not sure if it can be done in  4 one image. How can you represent the entire specimen  5 using one image? One image just represents the area.  6 Q. All right. Well, you have two  7 images here. Are the two images representative, when  8 taken together, of the entirety of the specimen with  9 regard to foreign-body type inflammation?  10 A. No, they cannot represent entire  11 specimen because they are just two images of two  12 specific areas.  13 Q. Are there areas with less foreign  14 body inflammation in the specimen?  15 A. Well, even in the image MS9 on page  16 22 we have one corner which has no foreign body  17 reaction. And then the middle part has quite extensive  18 collection of macrophages. So what happens, foreign  19 body responds, in most cases, does not envelope or does  20 not form a sheath around the mesh fibers. There's some  21 skip areas or patchy clusters of foreign body  22 macrophages or foreign-body type reaction. That's how  23 it is.  24 In some areas, the foreign body response</p>

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<p>1 is so permanent that it forms this confluent band along  2 the mesh fibers. Actually it becomes almost bridging  3 and in this case it is bridging. I mean, if we look at  4 MS10, the spacing between these fibers -- we can mark  5 them with star --  6 Q. Green star.  7 A. Green star. That space is actually  8 bridged by the foreign body reaction, so here we can  9 call it as bridging inflammation.  10 Q. Okay. Is that present throughout  11 the entirety of the specimen?  12 A. No, it's not. Again, some fossa  13 are like this; some fossa have less.  14 Q. What is the significance, if any,  15 of the bridging of the inflammation?  16 A. Just shows the extent of  17 inflammation that it's, it's so extensive in that  18 specific area that it bridges. The volume of  19 inflammation -- the more inflammation, the more damage  20 from inflammation, the more inflammatory mediators in  21 there, the more negative effects of the inflammation.  22 -- RECESS AT 9:39 --  23 -- RESUMING AT 9:51 --  24</p>	<p>1 description does the pathologist at Vanderbilt  2 University assess deformation in the mesh specimen?  3 A. There's no assessment for  4 deformation in the gross description.  5 Q. Okay. And the gross only here  6 means that the pathology department at Vanderbilt did  7 not submit the specimen for microscopic examination; is  8 that right?  9 A. That is correct.  10 Q. Okay. We can put that aside for  11 now. Is it your understanding in this case that  12 Ms. Stubblefield underwent four revision surgeries?  13 A. At least four from what I can see  14 in the summary.  15 Q. Okay. And you received a specimen  16 from one of these, only one of these surgeries; is that  17 correct?  18 A. That is correct.  19 Q. Have you received any other  20 specimens taken from Ms. Stubblefield other than from  21 the September 23rd, 2009, surgery?  22 A. No.  23 Q. And we talked about this briefly  24 earlier, but you had mentioned that a portion of the</p>
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<p>1 BY MR. SNOWDEN:  2 Q. All right. I'm going to hand you  3 what has been marked as Stubblefield four.  4 EXHIBIT NO. 4: Surgical Pathology Final  5 Report, reported 9/28/2009  6 MR. ZIMMERMAN: Thank you.  7 BY MR. SNOWDEN:  8 Q. If you look at the right-hand of  9 this surgical pathology report, see the collection date  10 of 9/23/2009?  11 A. I do.  12 Q. Does that correspond with the  13 specimen you received in this case?  14 A. Yes, it does.  15 Q. And if we look down under the  16 diagnosis it says, "Mesh excision synthetic material  17 consistent with surgical mesh (gross diagnosis only)."  18 Do you see that?  19 A. I do.  20 Q. Then there is a gross description  21 toward the bottom of the page that then continues on to  22 page 2. Do you see that?  23 A. I do.  24 Q. Okay. And anywhere in the gross</p>	<p>1 sling had been removed prior to September 23rd, 2009;  2 is that right?  3 A. That is correct.  4 Q. I want to hand you what I'm marking  5 as Stubblefield 5.  6 EXHIBIT NO. 5: Operative report  7 2007/01/04  8 MR. ZIMMERMAN: Thank you.  9 BY MR. SNOWDEN:  10 Q. And do you recognize this to be the  11 operative note from Ms. Stubblefield's surgery on  12 January 4, 2007?  13 A. Yes.  14 Q. Before we get too far into this,  15 let me ask you. Regarding your clinicopathological  16 correlation, do you have an opinion in this case  17 regarding the cause of Ms. Stubblefield's erosion?  18 A. Well, the erosion was caused by the  19 foreign body. So we -- as we discussed with other  20 specimens or other plaintiffs, because mesh cannot be  21 remodeled and cannot be modified, altered by the body,  22 it can erode. So it damages the tissue when it  23 migrates or prevents it from healing when there is  24 exposure of the mesh through the mucosa. Cannot be</p>

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<p>1 reabsorbed completely to seal off the area. So if</p> <p>2 there is foreign object in the wound, it will not heal.</p> <p>3 So this is the main feature, nature of</p> <p>4 the mesh as foreign body. That's why it erodes.</p> <p>5 That's why it becomes a chronically eroded wound.</p> <p>6 There is also whole set of other</p> <p>7 features in relation to the mesh, but those feature,</p> <p>8 features are of the tissue reaction. The scarring in</p> <p>9 the area and inflammation, they all work together with</p> <p>10 the mesh so they also have -- or they also contribute</p> <p>11 to all the changes.</p> <p>12 Q. And are you able to identify which</p> <p>13 of those factors was the cause of Ms. Stubblefield's</p> <p>14 erosions in this case?</p> <p>15 A. As I said, because they all occur</p> <p>16 at the same time, and they all occur due to the mesh</p> <p>17 placement, we cannot separate one single feature and</p> <p>18 then link it to one specific symptom. It's impossible.</p> <p>19 Everything occurs at the same time. They're all related</p> <p>20 to the mesh and ...</p> <p>21 Q. In your erosion section on page 11</p> <p>22 of your report, you have listed as one of the several</p> <p>23 factors in the mechanisms of erosion, you list</p> <p>24 infection. Do you see that? In your report?</p>	<p>1 A. No, I did not.</p> <p>2 Q. In this case you didn't see any</p> <p>3 acute inflammation in the specimen?</p> <p>4 A. No, I did not.</p> <p>5 Q. In this case you didn't see any</p> <p>6 signs of infection in the specimen?</p> <p>7 A. In my half what I examined, I did</p> <p>8 not.</p> <p>9 Q. On page 13 of your report under the</p> <p>10 polypropylene degradation section, you have there,</p> <p>11 "The degraded polypropylene formed a continuous</p> <p>12 brittle sheath around the mesh. Filaments contributing</p> <p>13 to mesh stiffening." Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. Did you do any mechanical testing</p> <p>16 of the mesh?</p> <p>17 A. I did not perform any destructive</p> <p>18 testing, either analytical chemistry or mechanical</p> <p>19 testing, because this would not give me opportunity to</p> <p>20 do histology. I used histological methods to observe</p> <p>21 features under the microscope, and then I can judge by</p> <p>22 the histological appearance or appearance of the</p> <p>23 polypropylene in this case under the microscope</p> <p>24 regarding its properties. And if something shatters or</p>
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<p>1 A. This would be --</p> <p>2 Q. Page 11.</p> <p>3 A. Page 11.</p> <p>4 Q. And it's just before the last</p> <p>5 paragraph on the page.</p> <p>6 A. Yes, I do.</p> <p>7 Q. Do you have an opinion in this case</p> <p>8 regarding whether Ms. Stubblefield had an infected mesh</p> <p>9 prior to -- strike that.</p> <p>10 Do you have an opinion in this case</p> <p>11 regarding whether Ms. Stubblefield had an infected mesh</p> <p>12 that led to an erosion?</p> <p>13 A. So regarding infection, an</p> <p>14 infection may not be present before the erosion or</p> <p>15 trigger the erosion. However, once the mesh is exposed</p> <p>16 or there is a breach of mucosal surface, the wound of</p> <p>17 mesh exposure becomes infected. And then that triggers</p> <p>18 acute inflammation, and then there is more damage of</p> <p>19 the tissue. Because it is inflamed and infected, the</p> <p>20 area cannot heal, so that becomes a contributing factor</p> <p>21 for continuing erosion. So it -- or expansion of the</p> <p>22 erosion.</p> <p>23 Q. Okay. In this case, you didn't</p> <p>24 have any mucosa in the specimen; is that right?</p>	<p>1 cracks, it indicates its brittleness, because the</p> <p>2 nondegraded core of the fibers does not crack while the</p> <p>3 degraded bark cracks.</p> <p>4 Therefore, it indicates that there is a</p> <p>5 change of physical properties which is due to</p> <p>6 degradation.</p> <p>7 Q. The next sentence you have,</p> <p>8 "Extensive cracking can also provide cavities to</p> <p>9 harbor bacteria as is well known in microporous</p> <p>10 meshes." Did you identify any bacteria in the cracking</p> <p>11 of the degradation layer in this case?</p> <p>12 A. As specimens, I do not search for</p> <p>13 individual bacteria. It's difficult to do in</p> <p>14 histological sections. I can identify bacteria when</p> <p>15 they are in colonies. Then it is more reliable.</p> <p>16 Q. In the second to last paragraph you</p> <p>17 have:</p> <p>18 "Degradation of a polymer also</p> <p>19 indicates its breakdown into smaller</p> <p>20 molecules. In cases of implanted</p> <p>21 materials, the products of degradation</p> <p>22 are released into the tissue adding to</p> <p>23 the complex pathological interactions</p> <p>24 between the mesh and the human body."</p>

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<p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. Did you identify any of those</p> <p>4 products of degradation released into the tissue in</p> <p>5 this case?</p> <p>6 A. We cannot because that would be</p> <p>7 destructive testing. And I don't know if there is any</p> <p>8 test to measure it in the tissue. All of the</p> <p>9 publications I have seen, they were measuring products</p> <p>10 of degradation in vitro when there was degradation of</p> <p>11 the polypropylene outside of the body.</p> <p>12 Q. Okay. On pages 32 -- strike that.</p> <p>13 Pages 26 of your report through page 32,</p> <p>14 is -- looks like it contains opinions regarding</p> <p>15 degradation layer?</p> <p>16 A. It does. I mean these pages, they</p> <p>17 describe the same features I described in the January</p> <p>18 report and other specimens as well.</p> <p>19 Q. Okay. And as I understand it,</p> <p>20 the -- is it your opinion that in MS13(a), for example,</p> <p>21 that the degradation bark takes up histologic dyes?</p> <p>22 A. That is correct.</p> <p>23 Q. To give it its purple color; is</p> <p>24 that right?</p>	<p>1 opinions?</p> <p>2 BY MR. SNOWDEN:</p> <p>3 Q. I'm asking if he has a new opinion</p> <p>4 regarding testing that has been ongoing in the case,</p> <p>5 which I think I'm entitled to ask.</p> <p>6 MR. ZIMMERMAN: Do you have a question</p> <p>7 about Ms. Stubblefield? Because it's a case-specific</p> <p>8 deposition that we're taking today.</p> <p>9 If you are asking for an update on the</p> <p>10 opinions that were elicited during his general</p> <p>11 deposition, it's outside of the scope of this</p> <p>12 deposition.</p> <p>13 BY MR. SNOWDEN:</p> <p>14 Q. I don't agree. It's part -- okay.</p> <p>15 Let me ask it this way.</p> <p>16 Dr. Iakovlev, for any of the cases in</p> <p>17 Wave 1 have you performed -- have you concluded your</p> <p>18 degradation -- strike that.</p> <p>19 For Ms. Stubblefield or any other cases</p> <p>20 involving Wave 1 plaintiffs, have you completed your</p> <p>21 experiment where you were attempting to intentionally</p> <p>22 oxidize polypropylene to see if it would take up</p> <p>23 histologic dyes?</p> <p>24 A. That experiment was not required to</p>
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<p>1 A. That is correct.</p> <p>2 Q. And if I understand your -- strike</p> <p>3 that.</p> <p>4 As I understand it, your opinion is that</p> <p>5 the reason that it uptakes the dye is that the outer</p> <p>6 layer is oxidized?</p> <p>7 A. Well, it takes up the dye because</p> <p>8 it is not solid any more. So there is some micro or</p> <p>9 nanopores and nanocavities which can absorb the dye.</p> <p>10 That's why it takes up the dye.</p> <p>11 Q. Okay. You've previously testified</p> <p>12 that you were -- you undertook an experiment to</p> <p>13 intentionally oxidize polypropylene and see whether it</p> <p>14 takes up histologic stain. Do you recall that?</p> <p>15 A. You mean from the general opinions?</p> <p>16 Q. Do you recall that?</p> <p>17 A. The discussion? Or the experiment?</p> <p>18 Q. The experiment.</p> <p>19 A. I do recall.</p> <p>20 Q. Okay. Have you concluded that</p> <p>21 experiment yet?</p> <p>22 A. So now at the end of last patient</p> <p>23 we are switching back to general opinions?</p> <p>24 MR. ZIMMERMAN: Are you asking general</p>	<p>1 detect degradation layer for any of these cases. It's</p> <p>2 done for completely different purpose.</p> <p>3 Q. Have you completed it?</p> <p>4 A. No, I have not completed it yet.</p> <p>5 Q. Do you plan to offer any opinions</p> <p>6 at trial regarding that experiment?</p> <p>7 A. For Ms. Stubblefield?</p> <p>8 Q. Yeah, for Ms. Stubblefield.</p> <p>9 A. No. For Ms. Stubblefield I will</p> <p>10 not use it. As I said, it's not required. And it's</p> <p>11 not needed. I'll do it for different purpose. That</p> <p>12 experiment is mainly to show that the model of in vitro</p> <p>13 degradation which can simulate in vivo degradation is</p> <p>14 usable. It's more of a testing of the model rather</p> <p>15 than confirming the degradation.</p> <p>16 Q. Dr. Iakovlev, on page 13 of your</p> <p>17 report you have, under the polypropylene degradation</p> <p>18 section, a paragraph that begins, "In</p> <p>19 Ms. Stubblefield's case, the mesh also fragmented in</p> <p>20 the body." Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. What's your opinion regarding when</p> <p>23 the mesh fragmented within her body?</p> <p>24 A. So if we go back to the</p>

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<p>1 intermediate excision, which was in 2007, one of 2 descriptions which was given in January, 2007, was this 3 material, because of its loose weave, fragmented 4 easily. So there is description of fragmentation 5 during that excision date which predated the excision 6 of the specimen I received.</p> <p>7 Now, if we go back to the images 8 beginning with MS17(a), there's a series of images 9 which shows fragments of polypropylene. Some of these 10 fragments are irregular, and they contain blue fiber -- 11 blue granules within or inside the fragments, and some 12 of the fragments are rectangular. And they correlate 13 with scales of the degradation bark.</p> <p>14 So what happened during the excision in 15 2007, some of the chips or small fragments of the mesh 16 were cut off. And when the mesh was cut off, some of 17 the bark fragments peeled off and formed this 18 scale-type fragments in the tissue.</p> <p>19 So we have a combination of portions of 20 the mesh fibers which were cut off from the nondegraded 21 core. For example, in picture MS17(a) on page 33, as 22 circled with green marker, that specific fragment was 23 from the nondegraded core. And it's together with the, 24 in the same sort of cluster of fragments with the</p>	<p>1 And it's clear -- I will use green 2 marker and outline the edges of the degradation bark 3 which formed on the surface of these fragments. And 4 the degradation bark is also birefringent on next page 5 36, so it behaves exactly the same way as degradation 6 bark which is formed on intact fibers or nonfragmented 7 fibers.</p> <p>8 And if we check, the excision in 2007 9 occurred approximately two years after implementation. 10 So by two years, the bark was of sufficient thickness 11 to be visible and to peel off the nondegraded core. 12 Then when the nondegraded core fragments were left in 13 2007 by the excision I received specimen of, which was 14 another two years after the intermediate excision, 15 these fragments which I circled on page 35, they were 16 exposed to the body environment long enough to form 17 their own degradation bark.</p> <p>18 Q. The fragments in MS18(a), how large 19 are those?</p> <p>20 A. Well, I don't know if it's a whole 21 fragment here or just like a tip of the iceberg. It's 22 hard to say. What I can say is what the cross section 23 or estimate the cross section, longest diameter what we 24 see in this section.</p>
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<p>1 scales of the bark.</p> <p>2 So what happened, both the degraded bark 3 was fragmented during the excision and the nondegraded 4 core was also fragmented to a degree, with scissors or 5 with other tools. And we see the combination of this 6 too.</p> <p>7 And if we flip the page to page 34, we 8 can see the appearance of these fragments in polarized 9 light. For example, the fragment which has distinct 10 rectangular shape -- I'm circling it with blue 11 marker -- also shows transverse cracks. So this is 12 typical for degradation bark, where the particle of 13 nondegraded core does not show -- and I also circled it 14 with blue marker but it's difficult to see because it's 15 dark background. It does not have any cracking. It's 16 solid, because it's not degraded -- at least it's not 17 degraded in the middle.</p> <p>18 What's interesting if we flip the page 19 to page 35, image MS18(a) shows another two or three 20 particles of the nondegraded core which were cut off 21 the mesh during previous excision. And now we can see 22 actually that these fragments of the nondegraded core 23 were left in the body at that time formed their own 24 degradation bark.</p>	<p>1 I would estimate it is approximately 2 50-microns long. Maybe less, maybe 30, somewhere 3 between 30 and 50.</p> <p>4 Q. And how wide is it?</p> <p>5 A. 15 microns. Again, it's rough 6 estimate.</p> <p>7 So overall when there is a cluster of 8 these fragments, it's a combination of scales of the 9 bark and fragments of nondegraded core, which was 10 nondegraded in 2007. By 2009 there is a degradation 11 bark in each of those fragments.</p> <p>12 Q. And what's the significance, if 13 any, of this to your opinion?</p> <p>14 A. Well, it's all just consistent with 15 previously-described findings regarding degradation 16 bark. It's fragile. It cracks. Cracks and then forms 17 this scale-like particles which were deposited in the 18 tissue. Also it forms on any polypropylene of any 19 shape, either cylindrical shape of intact fibers or 20 fibers like this depicted in MS18(a).</p> <p>21 Q. And what's your basis for the 22 opinion that portions of what we see in these figures 23 are fragments of bark rather than pieces of mesh that 24 are dislodged during cutting at the excision procedure?</p>

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<p>1 A. Shape. Shape and absence of -- or</p> <p>2 relative absence of the blue granules, because when</p> <p>3 material degrades, blue granules degrade as well. So</p> <p>4 if we see rectangular shape, which represents cross</p> <p>5 section of a scale, and relative lack of the blue</p> <p>6 granule, it means that the material was degraded</p> <p>7 before, formed degradation bark, and then was</p> <p>8 fragmented further and was left in the body.</p> <p>9 Q. How do you rule out the absence,</p> <p>10 that the absence of blue granules was due to the fact</p> <p>11 that Prolene soft has both blue and clear filaments?</p> <p>12 A. Some of it can be because of the</p> <p>13 clear filaments. Some of it, you -- we can actually</p> <p>14 see some residual blue granules in some of the</p> <p>15 fragments. It depends on what fiber they are coming</p> <p>16 from. If they are coming from clear fibers, there was</p> <p>17 no blue granules at the beginning.</p> <p>18 For example, on page 37, there's few</p> <p>19 scales of the bark forming this curvilinear scales, and</p> <p>20 we see the blue granules within them. So in that</p> <p>21 specific area, a blue fiber was crushed, and then the</p> <p>22 bark peeled off and left these scales in the area.</p> <p>23 Q. And what's your basis for the</p> <p>24 opinion that this all occurred in the 2007 surgery?</p>	<p>1 Q. Have you ever done a controlled</p> <p>2 experiment where you take a pristine Prolene soft mesh</p> <p>3 and cut it and see what, if any, particles come off the</p> <p>4 mesh?</p> <p>5 A. I'm not sure what would be the</p> <p>6 purpose of this experiment. That -- does it imply that</p> <p>7 it is impossible to make smaller fragments? Sometimes</p> <p>8 I cut the mesh fibers and I can see what fragments are</p> <p>9 left or the crushed ends of the mesh.</p> <p>10 I examined the meshes. When the</p> <p>11 pristine mesh is cut and I see the edges, and I can see</p> <p>12 clearly, especially in the places where short segment</p> <p>13 of the fiber is still attached, can see it's kind of</p> <p>14 loose. If it's outside of the body, if it's very small</p> <p>15 fragment, it will just snap off and become dislodged.</p> <p>16 So I've seen larger portions of the mesh</p> <p>17 fibers still attached to the mesh after the cutting.</p> <p>18 Q. And my question was whether you</p> <p>19 have done a controlled experiment where you take a</p> <p>20 pristine Prolene soft mesh, cut it, and determine what</p> <p>21 particles, if any, come off the mesh.</p> <p>22 A. So my answer would be I did examine</p> <p>23 meshes after cutting them with scissors, and I did see</p> <p>24 some larger portions of the fibers left on the mesh.</p>
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<p>1 A. Just analysis of the records. This</p> <p>2 occurred sometime before the excision in 2009. So</p> <p>3 there was an event sometime between implantation and</p> <p>4 excision in 2009 which crushed the fibers to produce</p> <p>5 first of all scales of bark and, at the same time,</p> <p>6 fragment the nondegraded core. And the only event I</p> <p>7 can see in the records is excision in 2007.</p> <p>8 Q. Did you consider the fact that the</p> <p>9 mesh is cut during placement?</p> <p>10 A. But during the placement there is</p> <p>11 no degradation layer. Wouldn't produce this</p> <p>12 perfectly rectangular scales or cross sections of</p> <p>13 the scales.</p> <p>14 I think we had one case -- I don't know</p> <p>15 if it was you during the deposition -- where there were</p> <p>16 some fragments which were triangular and some irregular</p> <p>17 shape. So when the fragment is triangular shape, it</p> <p>18 can be coming -- or can be embedded in the tissue</p> <p>19 during implantation. If it's rectilinear and if it's</p> <p>20 consistent with the bark, the only way to produce this</p> <p>21 is to leave the mesh in the body long enough so the</p> <p>22 bark is formed and then crush the fibers, produce those</p> <p>23 scales, and leave it in the body again for some time so</p> <p>24 there will be vital reaction around it.</p>	<p>1 They were loose. They were loosely attached so they</p> <p>2 fall out easily because they are not -- you need a long</p> <p>3 fiber which is being held in the weave pattern of the</p> <p>4 mesh.</p> <p>5 Q. Did you then take those pieces and</p> <p>6 process them through tissue processing to analyze their</p> <p>7 shape and the presence of degradation bark?</p> <p>8 A. Well, I can see the shape in the</p> <p>9 microscope because when I examined it, I examine it in</p> <p>10 the microscope without embedding.</p> <p>11 Q. And have you ever -- first off, do</p> <p>12 you know what tool the implanting surgeon used to cut</p> <p>13 the mesh in this case?</p> <p>14 A. We can check with the excision</p> <p>15 record from 2007.</p> <p>16 MR. ZIMMERMAN: Exhibit 3. I'm sorry.</p> <p>17 THE DEPONENT: Is it 2007?</p> <p>18 MR. ZIMMERMAN: Five.</p> <p>19 THE DEPONENT: So where is 2007? Here.</p> <p>20 BY MR. SNOWDEN:</p> <p>21 Q. I'm sorry. My first question is:</p> <p>22 Do you know what tool the surgeon who implanted the</p> <p>23 mesh to be Exhibit 3, what tool he used to form the</p> <p>24 mesh into a six inch by half inch sling?</p>

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<p style="text-align: right;">Page 74</p> <p>1 A. Scissors. Does not say exactly</p> <p>2 which tool, but most likely scissors.</p> <p>3 Q. So sitting here today, you won't</p> <p>4 know whether you have replicated the same type of</p> <p>5 cutting in your lab as the surgeon implanting the mesh</p> <p>6 used in forming the sling in this case?</p> <p>7 A. But I'm not using this experiment.</p> <p>8 I do not need this experiment to formulate my opinions.</p> <p>9 I arrive to my opinions examining the specimen. The</p> <p>10 effect of what happened. I'm not -- I don't need an</p> <p>11 experiment to actually determine that these are</p> <p>12 fragments of polypropylene. Some of it is completely</p> <p>13 degraded; some of it is partially still containing</p> <p>14 nondegraded core. I can see it in the images, and I</p> <p>15 saw it in the specimen itself.</p> <p>16 Q. And that wasn't my question. My</p> <p>17 question was: Sitting here today, you do not know</p> <p>18 whether you employed the same type of cutting of a mesh</p> <p>19 in your lab as the implanting physician used when he</p> <p>20 formed the Prolene soft into a sling in this case?</p> <p>21 A. As I said, I did not need this</p> <p>22 experiment. I did not perform it.</p> <p>23 Q. Okay.</p> <p>24 A. Because I'm describing the effect</p>	<p style="text-align: right;">Page 76</p> <p>1 tool.</p> <p>2 Q. And motion to strike that answer as</p> <p>3 nonresponsive.</p> <p>4 Regarding the January 4th, 2007,</p> <p>5 procedure, do you know what tool was used to cut the</p> <p>6 mesh?</p> <p>7 A. The record describes that the</p> <p>8 material was fragmented easily, but it does not say</p> <p>9 exactly what tool was used at that time. Whatever tool</p> <p>10 was used, it fragmented the mesh.</p> <p>11 Q. So regarding the January 4th, 2007,</p> <p>12 procedure where mesh was removed, you do not know</p> <p>13 whether you have performed an experiment in your lab</p> <p>14 where you have cut a pristine mesh using the same tool</p> <p>15 as that used to cut the mesh in this procedure to</p> <p>16 determine the shape or presence of any particles; is</p> <p>17 that correct?</p> <p>18 MR. ZIMMERMAN: Objection.</p> <p>19 THE DEPONENT: It's not what I do. I</p> <p>20 don't do specific experiments as for any other</p> <p>21 specimens. What I do, I describe the histological</p> <p>22 feature, what is abnormal in the tissue. In this case,</p> <p>23 I described this particle and it's unequivocal. There</p> <p>24 are particles of the polypropylene. Some of them are</p>
<p style="text-align: right;">Page 75</p> <p>1 of it, not specifically how it was formed. I can see</p> <p>2 clearly that these are particles of polypropylene.</p> <p>3 Q. And then you would agree that you</p> <p>4 have not performed an experiment where you use the same</p> <p>5 cutting method on a pristine Prolene soft mesh to</p> <p>6 determine the shape or presence of any particles that</p> <p>7 would come off of that mesh?</p> <p>8 A. I don't understand how would that</p> <p>9 experience -- experiment contribute to the opinions.</p> <p>10 We already observed that there are particles in the</p> <p>11 tissue.</p> <p>12 Q. And that's not my question, Doctor.</p> <p>13 Would you agree that you have not performed an</p> <p>14 experiment where you use the same cutting method on a</p> <p>15 pristine Prolene soft mesh to determine the shape or</p> <p>16 presence of any particles that would come off the mesh</p> <p>17 as a result?</p> <p>18 A. I did not need that experiment and</p> <p>19 I did not perform it.</p> <p>20 Q. And regarding the January 4th,</p> <p>21 2007, procedure where mesh was removed, do you know</p> <p>22 what tool was used to cut the mesh?</p> <p>23 A. All I can say, whatever tool was</p> <p>24 used, the mesh was fragmented under the use of that</p>	<p style="text-align: right;">Page 77</p> <p>1 rectangular, describing -- or consistent with scales,</p> <p>2 and some of them are irregular, larger particles.</p> <p>3 So my opinions are based on the</p> <p>4 examination and analysis of the specimen itself, not on</p> <p>5 additional experimentation.</p> <p>6 BY MR. SNOWDEN:</p> <p>7 Q. Doctor with -- strike that.</p> <p>8 Sitting here today, you would not be</p> <p>9 able to tell the ladies and gentlemen of the jury</p> <p>10 whether or not you performed a control experiment using</p> <p>11 the same method of cutting a pristine mesh as that used</p> <p>12 by the doctor who cut the mesh in the January 4th,</p> <p>13 2007, procedure, correct?</p> <p>14 MR. ZIMMERMAN: Objection. Answer if</p> <p>15 you can.</p> <p>16 THE DEPONENT: So the answer would be</p> <p>17 that, as for all diagnostic specimens, we do not</p> <p>18 require a control. We assess the specimens for the</p> <p>19 difference what is expected in the tissue, either</p> <p>20 normal tissue or altered to a degree.</p> <p>21 So in this case, what I can use as a</p> <p>22 description of what is expected would be several</p> <p>23 hundred of the specimens I examined of explanted</p> <p>24 measures. This is the first time I see such an extent</p>

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<p style="text-align: right;">Page 78</p> <p>1 of scales of the bark in the tissue. It's not -- it</p> <p>2 was not expected. This wasn't -- somewhat unexpected</p> <p>3 finding, and it's completely different from other</p> <p>4 specimens. And we saw the particles of the measure in</p> <p>5 the tissue only in the occasional cases.</p> <p>6 BY MR. SNOWDEN:</p> <p>7 Q. And in all due respect, I'm not</p> <p>8 sure whose question you are answering.</p> <p>9 Doctor, would you be able to tell the</p> <p>10 ladies and gentlemen of the jury whether or not you</p> <p>11 performed a control experiment using the same method of</p> <p>12 cutting a pristine mesh as used by the doctor who cut</p> <p>13 the mesh in the January 4th, 2007, procedure?</p> <p>14 A. I did not need to do an experiment,</p> <p>15 separate experiment, and that's not what we do as</p> <p>16 pathologists to do experiment every time we see some</p> <p>17 features under the microscope. We ...</p> <p>18 Q. And I'm not asking you whether you</p> <p>19 needed to do it. I'm asking you whether you did such a</p> <p>20 controlled experiment.</p> <p>21 A. That's why I did not do it.</p> <p>22 Q. Okay. So we agree you didn't do</p> <p>23 it?</p> <p>24 A. I did not require and I did not do</p>	<p style="text-align: right;">Page 80</p> <p>1 observation of multiple particles in the tissue,</p> <p>2 because, as I said, the finding is not common. It's</p> <p>3 not commonly seen. And the description in the records</p> <p>4 is not common as well.</p> <p>5 And it correlates logically and</p> <p>6 pathophysiologically and it correlates also with my</p> <p>7 understanding of the behavior of polypropylene in the</p> <p>8 body and formation of the bark and behavior of the</p> <p>9 bark.</p> <p>10 Q. Why do you -- well first off, did</p> <p>11 the physician here during this surgery mention</p> <p>12 particles coming off the mesh?</p> <p>13 A. Fragmented. Fragments.</p> <p>14 Q. So is that the same as particle?</p> <p>15 A. Well fragment is a particle.</p> <p>16 Q. Would a one centimeter portion of</p> <p>17 the mesh also be a fragment?</p> <p>18 A. I don't think the surgeon would</p> <p>19 describe one centimeter as a fragment and fragmented</p> <p>20 easily.</p> <p>21 Q. Why did you mention loose weave in</p> <p>22 relation to fragments? What does that have to --</p> <p>23 sorry, strike that.</p> <p>24 If you are correct, why did the doctor</p>
<p style="text-align: right;">Page 79</p> <p>1 it.</p> <p>2 Q. You have mentioned several times a</p> <p>3 statement from the January 4th, 2007, operative note</p> <p>4 mentioning this material, because of its loose weave,</p> <p>5 fragmented easily. Do you know what this -- do you</p> <p>6 know if this doctor was deposed in this case?</p> <p>7 A. No.</p> <p>8 Q. If he was deposed, do you have any</p> <p>9 idea what he said?</p> <p>10 A. No.</p> <p>11 Q. How do you -- what's the basis for</p> <p>12 your belief that what he is describing there are the</p> <p>13 particles you see in your specimen?</p> <p>14 A. This is first time, after more than</p> <p>15 200 specimens, I see such a description by the surgeon</p> <p>16 that the material fragmented easily. This is also the</p> <p>17 first time I see a number of particles in such an</p> <p>18 extent.</p> <p>19 So to a reasonable degree of medical</p> <p>20 probabilities, the likelihood of these two facts are</p> <p>21 not related is very low. So to a reasonable degree of</p> <p>22 medical probability, I can state that there is very --</p> <p>23 very high likelihood that the description of the</p> <p>24 surgeon of fragmented mesh correlates with my</p>	<p style="text-align: right;">Page 81</p> <p>1 mention loose weave in regards to particles that you</p> <p>2 see in your specimen?</p> <p>3 MR. ZIMMERMAN: Objection, answer if you</p> <p>4 can.</p> <p>5 THE DEPONENT: I'm not sure what he</p> <p>6 meant. We would have to ask him. I can say that he</p> <p>7 noticed that it was fragmented easily, so he had some</p> <p>8 difficulty excising it in one piece, and there was</p> <p>9 extra manipulations in the area.</p> <p>10 BY MR. SNOWDEN:</p> <p>11 Q. And how did you rule out, if you</p> <p>12 did, the -- whether what the surgeon was referring to</p> <p>13 was the mesh coming out in pieces?</p> <p>14 A. Well I can only say what is in the</p> <p>15 records, and the record clearly states "fragmented".</p> <p>16 Q. Okay. And is fragmented also</p> <p>17 consistent with mesh coming out in four pieces?</p> <p>18 A. You would have to ask the</p> <p>19 explanting surgeon.</p> <p>20 Q. Okay. You didn't care to read the</p> <p>21 deposition of that doctor in this case, correct?</p> <p>22 MR. ZIMMERMAN: Objection.</p> <p>23 THE DEPONENT: This is not correct that</p> <p>24 I did not care. I do not read depositions for any of</p>

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<p>1 the cases at least for Wave 1. I read depositions only</p> <p>2 in very rare occasions where there is significant</p> <p>3 discrepancy between the records and I need to clarify</p> <p>4 which record is correct.</p> <p>5 BY MR. SNOWDEN:</p> <p>6 Q. I'm handing you what is marked as</p> <p>7 Stubblefield 6.</p> <p>8 EXHIBIT NO. 6: Surgical Pathology</p> <p>9 Report reported on 2007/01/10</p> <p>10 BY MR. SNOWDEN:</p> <p>11 Q. Doctor, if you take a look at this</p> <p>12 surgical pathology report, is it your understanding</p> <p>13 this relates to the mesh removal from January 4th,</p> <p>14 2007?</p> <p>15 A. That's correct.</p> <p>16 Q. Okay. And if we go down to the --</p> <p>17 well first off, do you see any mention of particles in</p> <p>18 this pathology description?</p> <p>19 A. There is no microscopy. There is</p> <p>20 only gross description.</p> <p>21 Q. Would you need a microscope to see</p> <p>22 the particles?</p> <p>23 A. Yes, of those particles I describe,</p> <p>24 they would not be visible without microscope.</p>	<p>1 A. And wasn't as strong.</p> <p>2 Q. So what the doctor on January 4th,</p> <p>3 2007, when he was explanting the mesh and he said this</p> <p>4 material, because of its loose weave, fragmented</p> <p>5 easily, it's your testimony and your opinion he wasn't</p> <p>6 identifying the particles you see under the microscope?</p> <p>7 A. That is correct, he wouldn't be</p> <p>8 able to see it. But the fact is that the excision was</p> <p>9 piecemeal. There were multiple cuts and more</p> <p>10 manipulations describes higher risk for fragmentation</p> <p>11 at microscopic level.</p> <p>12 Q. Okay. And this pathology report,</p> <p>13 does it mention the mesh being deformed?</p> <p>14 A. There is no description of the</p> <p>15 configuration of the mesh either way, if it's deformed</p> <p>16 or flat.</p> <p>17 Q. In your opinion regarding pain</p> <p>18 starting on page 12, you have on the third paragraph in</p> <p>19 that section:</p> <p>20 "There was a foreign body type</p> <p>21 inflammatory reaction to the mesh.</p> <p>22 Additionally, the mesh fragmented at one</p> <p>23 point and introduced collections of</p> <p>24 smaller particles."</p>
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<p>1 Q. Okay. So the doctor saw the</p> <p>2 fragments or particles during the surgery but the</p> <p>3 pathologist would need a microscope to see it?</p> <p>4 A. I did not say that the doctor saw</p> <p>5 fragments. He said it was fragmented easily meaning</p> <p>6 that he had to do multiple cuts to remove the mesh or</p> <p>7 that he had difficulty removing it in one piece.</p> <p>8 That's what it means.</p> <p>9 It does not specifically indicate that</p> <p>10 he could see the fragments which were produced during</p> <p>11 that procedure because, again, it's microscopic and</p> <p>12 it's in the tissue.</p> <p>13 Q. So you would agree with me then</p> <p>14 that the statement that the mesh, because of its loose</p> <p>15 weave, fragmented easily is consistent with the</p> <p>16 pathology report showing the mesh was removed in four</p> <p>17 pieces?</p> <p>18 A. Yes, it is.</p> <p>19 Q. Okay.</p> <p>20 A. It is. So he could not remove it</p> <p>21 in one piece. He had to do several smaller excisions</p> <p>22 because it was fragmented. So there was more</p> <p>23 manipulations in the area.</p> <p>24 Q. Okay.</p>	<p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. You say, "The latter amplified the</p> <p>4 burden of foreign body reaction in the tissue." Do you</p> <p>5 see that?</p> <p>6 A. I do.</p> <p>7 Q. What role, if any, did the</p> <p>8 collection of particles play in the pain that</p> <p>9 Ms. Stubblefield experienced?</p> <p>10 A. As with all other features, we</p> <p>11 shouldn't single out one feature and try to connect it</p> <p>12 to a specific symptom. This was all happening at the</p> <p>13 same time in the same mesh. It definitely didn't</p> <p>14 reduce the amount of changes. The additional particles</p> <p>15 increased the amount of foreign body reaction, so they</p> <p>16 amplified already abnormal finding.</p> <p>17 Q. How large was the field of</p> <p>18 particles -- strike that. Were the particles all in</p> <p>19 one area in the specimen?</p> <p>20 A. No. As far as my recollection,</p> <p>21 there were several fossa of these particles.</p> <p>22 Q. And how large was the area where</p> <p>23 the particles were located?</p> <p>24 A. I did not measure it. If I had the</p>

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<p>1 slides, I would point where the areas are.</p> <p>2 Q. How significant was the tissue</p> <p>3 reaction to the particles that you saw?</p> <p>4 A. It was quite significant. There</p> <p>5 was detectable foreign-body type reaction. We can see</p> <p>6 it in the images. If we go to, for example, page 37,</p> <p>7 you can see several macrophages in the area.</p> <p>8 Q. 100X objective, is that equivalent</p> <p>9 to a thousand times magnification?</p> <p>10 A. That's correct.</p> <p>11 Q. Every picture you have of the</p> <p>12 particles in your report is that a thousand times</p> <p>13 magnification?</p> <p>14 A. It is.</p> <p>15 Q. Okay. So you are not able to,</p> <p>16 sitting here today with your report that you have</p> <p>17 provided in this case, show us a picture that sort of</p> <p>18 shows the extent of any one of these particle fields?</p> <p>19 A. Not required. Wouldn't contribute</p> <p>20 either way.</p> <p>21 Q. I'm just trying to figure out how</p> <p>22 large it is. It sounds like I'm not going to be able</p> <p>23 to do today.</p> <p>24 A. Well, it wasn't my purpose to</p>	<p>1 bilateral groin pain. Again, it's not clear what it is</p> <p>2 attributed to. And then in 2000 -- again in 2005 in</p> <p>3 July, low back pain and suprapubic tenderness, some</p> <p>4 description of pain, however, there is no firm</p> <p>5 conclusion yet at the time that the pain is related to</p> <p>6 the mesh.</p> <p>7 And then later on in July 2005, it says</p> <p>8 pain in the mesh area.</p> <p>9 So about five months after implantation</p> <p>10 examination showed or connected pain with the mesh.</p> <p>11 EXHIBIT NO. 7: Progress Notes, dated</p> <p>12 3/18/05 to 7/8/05</p> <p>13 BY MR. SNOWDEN:</p> <p>14 Q. All right. I'm handing you what</p> <p>15 has been marked as Stubblefield 7.</p> <p>16 And if you look on the left-hand side,</p> <p>17 it says 3/18/05. Does this correlate with your entry</p> <p>18 on page 2 for March 18th, 2005?</p> <p>19 A. Yes.</p> <p>20 Q. All right. And I'm just trying to</p> <p>21 figure out this record here. It says, there's a</p> <p>22 urinalysis section and just below that it says, "Having</p> <p>23 a little leakage." Do you see that?</p> <p>24 A. Uhm-hmm.</p>
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<p>1 measure it. If, when you ship the slides back to me, I</p> <p>2 would be able to show the areas and measure them, but I</p> <p>3 mean since it wasn't my purpose, I did not do it when I</p> <p>4 had the slides.</p> <p>5 Q. Off the record.</p> <p>6 -- OFF THE RECORD AT 10:49 --</p> <p>7 -- RESUMING AT 10:52 --</p> <p>8 BY MR. SNOWDEN:</p> <p>9 Q. Dr. Iakovlev, are you aware --</p> <p>10 strike that. Is it important to your opinion in</p> <p>11 this -- well, strike that.</p> <p>12 Do you have any opinions in this case</p> <p>13 regarding when Ms. Stubblefield's pain, that's</p> <p>14 attributed to mesh, began?</p> <p>15 A. This question is best answered</p> <p>16 going through the records. So there is -- if we go</p> <p>17 into the records and implantation is February 2005, and</p> <p>18 then in March of 2005, which is a postoperative period,</p> <p>19 there is a description of pain with some movement</p> <p>20 "otherwise healed well." So it's not clear if that</p> <p>21 pain was related to the surgery or to the mesh but</p> <p>22 there is an entry there.</p> <p>23 And then in April, which is almost three</p> <p>24 months after surgery, there is a description of</p>	<p>1 Q. What's that -- what is that next --</p> <p>2 on the next line, what does that say?</p> <p>3 A. "P with some movement."</p> <p>4 Q. Okay. What's that P mean?</p> <p>5 A. Pain. I think I've seen it in --</p> <p>6 in other records. So I interpreted it as pain.</p> <p>7 Q. Okay. Is that a common medical</p> <p>8 abbreviation for -- P for pain?</p> <p>9 A. Sometimes it's used.</p> <p>10 Q. Okay. And -- okay. And then the</p> <p>11 next line says, "Well healed otherwise," right?</p> <p>12 A. Yes.</p> <p>13 Q. I'm done with that one. You can</p> <p>14 put it aside.</p> <p>15 Do you know -- do you have an opinion in</p> <p>16 this case regarding whether, if at all,</p> <p>17 Ms. Stubblefield's pain changed throughout the course</p> <p>18 of her treatment?</p> <p>19 MR. ZIMMERMAN: Objection, form. Answer</p> <p>20 if you can.</p> <p>21 THE DEPONENT: Well, the pain is</p> <p>22 changing because of the treatments. We can see that,</p> <p>23 for example, October, 2007, on page 5, she does not --</p> <p>24 some residual pain on anterior side where she had the</p>

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<p>1 mesh implant. So it indicates that at that time there</p> <p>2 is residual pain or there is some reduction of the pain</p> <p>3 after nerve blocks.</p> <p>4 So at least at that time there was a</p> <p>5 change in the pain.</p> <p>6 BY MR. SNOWDEN:</p> <p>7 Q. Okay. Any other changes to the</p> <p>8 pain?</p> <p>9 MR. ZIMMERMAN: Same objection. Answer</p> <p>10 if you can.</p> <p>11 THE DEPONENT: So again another entry on</p> <p>12 page 7, March 2011:</p> <p>13 "She went for three years with</p> <p>14 constant bilateral groin, suprapubic,</p> <p>15 and vaginal pain which she describes as</p> <p>16 'burning' like 'needles,' and 'jabbing</p> <p>17 pain'. She was treated by Dr. Zimmerman</p> <p>18 with excision of mesh and states that</p> <p>19 after the excision, the vaginal and</p> <p>20 midline pain went away. She is still</p> <p>21 stuck with the [bilateral lower</p> <p>22 quadrant] pain."</p> <p>23 So the location changed after the</p> <p>24 excision. That's another change in the pattern of pain</p>	<p>1 are working up their differential diagnosis. They make</p> <p>2 decision to excise mesh or to treat with specific</p> <p>3 interventions like nerve blocks, but especially</p> <p>4 excision of the mesh. If there is change of the</p> <p>5 symptoms after mesh excision, it just gives an extra</p> <p>6 evidence that symptoms pre-excision were caused by the</p> <p>7 mesh. Because the mesh was excised, symptoms were</p> <p>8 relieved, therefore, symptoms before the excision were</p> <p>9 caused by the mesh.</p> <p>10 Q. Does it matter to your differential</p> <p>11 diagnosis in this case -- strike that.</p> <p>12 Would it be important to your</p> <p>13 differential diagnosis in this case to know that the</p> <p>14 plaintiff later reported to healthcare providers that</p> <p>15 the surgeries had not addressed her pain?</p> <p>16 MR. ZIMMERMAN: Objection. Answer if</p> <p>17 you can.</p> <p>18 THE DEPONENT: As I said, I'm not doing</p> <p>19 clinical differential diagnosis. I just see what is in</p> <p>20 the records. I'm doing my morphological differential</p> <p>21 diagnosis.</p> <p>22 BY MR. SNOWDEN:</p> <p>23 Q. What's the difference between a</p> <p>24 clinical differential diagnosis and a morphological</p>
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<p>1 again, following treatment procedure.</p> <p>2 Again another entry, June, 2011:</p> <p>3 "67 year old female who presents for</p> <p>4 evaluation and management of pelvic</p> <p>5 pain. Patient was last seen by me a few</p> <p>6 months ago with the following diagnosis</p> <p>7 and treatment plan: Chronic neuropathic</p> <p>8 pain due to post-mesh pain syndrome.</p> <p>9 Partially relieved with nortriptyline,</p> <p>10 but patient could not tolerate it due to</p> <p>11 side effects."</p> <p>12 So, again, there was improvement of pain</p> <p>13 on medication, but patient could not tolerate the</p> <p>14 medication.</p> <p>15 But there is a change in pain, again,</p> <p>16 after treatment.</p> <p>17 BY MR. SNOWDEN:</p> <p>18 Q. What role, if any, did your</p> <p>19 evaluation of changes and complaints of pain have on</p> <p>20 your opinion?</p> <p>21 A. It's not in my opinion, but I can</p> <p>22 see the pattern in the records that if there is a</p> <p>23 specific treatment in relation to mesh, there is a</p> <p>24 change of symptoms. So I can see that the clinicians</p>	<p>1 differential diagnosis?</p> <p>2 A. Clinical differential diagnosis is</p> <p>3 being worked up by clinical investigations, by taking</p> <p>4 history, by examining the patient, doing some tests,</p> <p>5 radiological or imaging studies. Morphological</p> <p>6 differential diagnosis is determining what is abnormal</p> <p>7 in the excised tissue.</p> <p>8 If clinical differential diagnosis</p> <p>9 narrows the cause of specific symptoms to specific area</p> <p>10 and then it's being excised, I can look at the tissue</p> <p>11 in the microscope and I can say what is abnormal in the</p> <p>12 tissue. So then I can differentiate, is it natural</p> <p>13 disease like a tumor? Is it a foreign body? And what</p> <p>14 are the changes related to the foreign body? And then</p> <p>15 I can complete the diagnostic process which started</p> <p>16 with clinical differential diagnosis.</p> <p>17 Q. On page 12 of your report under the</p> <p>18 pain section, the first paragraph you end with "There</p> <p>19 was a relief of symptoms after mesh excision." Do you</p> <p>20 see that?</p> <p>21 A. Yes.</p> <p>22 Q. Is it important to your</p> <p>23 clinico-pathologic correlation in this case that there</p> <p>24 was a relief of symptoms after mesh excision?</p>

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<p>1 A. It's not required. And this is an 2 extra or additional information in the clinical 3 records. 4 Q. Are you relying on that fact in 5 your opinion in this case? 6 A. No. I'm relying on the fact that 7 clinical differential diagnosis lead to mesh excision, 8 and then my examination of the specimen when, when it 9 was removed or what was abnormal in the tissue at the 10 time of removal. And what I see in the tissue is 11 presence of the mesh and tissue reaction to the mesh. 12 Q. Were you provided with records from 13 Therapy Works in Winchester, Tennessee, where 14 Ms. Stubblefield reported that her surgeries have not 15 helped and was told that there was nothing else they 16 could do for her, in October of 2011? 17 A. What provider? 18 Q. Therapy Works. 19 A. I don't remember exact all the 20 records by heart. If it's on the thumb drive, I was 21 provided. If it's not there, then I did not have them. 22 Q. In any event, sounds like that 23 would not have been important to your opinion in this 24 case.</p>	<p>1 is the operative report from the mesh removal surgery 2 on that date? 3 A. Yes. 4 Q. Okay. And if we go down to the 5 last paragraph in the -- on this first page, it 6 mentions that, "A permanent suture was palpated on the 7 left side of the fascia penetrating the muscle and the 8 fascia." Do you see that? 9 A. Yes, I do. 10 Q. And then it says that "The suture 11 was attached to a remnant of the TVT mesh." Do you see 12 that? 13 A. I do. 14 Q. And we know what they mean there is 15 actually the Prolene soft that turned into a sling? 16 A. Yes. 17 Q. Okay. Then it continues and it 18 says: 19 "A second suture was located on the 20 right side of the fascia and the 21 dissection was carried out similarly." 22 Do you see that? 23 A. Sorry. I'm so tired, I barely can 24 see.</p>
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<p>1 MR. ZIMMERMAN: Objection. 2 THE DEPONENT: Just copy what is in the 3 clinical records. At the end of the day the decision 4 was to excise the mesh. 5 BY MR. SNOWDEN: 6 Q. During the procedure on 7 September 23rd, 2009, was the -- and that's the 8 specimen you have that relates to that procedure, 9 correct? 10 A. Yes. 11 Q. Was the mesh the only thing removed 12 that day from Ms. Stubblefield? 13 A. There were several fragments of 14 mesh removed at that time together with the tissue. 15 Q. Okay. 16 EXHIBIT NO. 8: Urology Gynecology 17 Operative Report 2009/09/23 18 BY MR. SNOWDEN: 19 Q. I'm handing you what is marked as 20 Stubblefield 8. And if you look at the top, you'll see 21 "Urology Gynecology Operative Report" 2000 -- well, 22 September 23rd, 2009. Do you see that? 23 A. I do. 24 Q. Okay. And do you understand this</p>	<p>1 Q. I skipped a sentence about removing 2 the mesh just so I could focus on the suture. So it 3 continues, "The mesh was carefully dissected." Do you 4 see that sentence? 5 A. Which line from the bottom? 6 Q. We are -- the line I want to look 7 at is three lines up from the bottom. 8 And it -- there's a line before it that 9 says the mesh was removed intact. Do you see that? 10 A. Yes, I do. 11 Q. The next is, "A second suture was 12 located on the right side of the fascia and the 13 dissection was carried out similarly." 14 Do you see that? 15 A. I do. 16 Q. Do you understand these to be the 17 tensioning sutures that -- strike that. 18 Do you understand these to be the 19 sutures found in your gross specimen pictures MS1? 20 A. I don't know if those were the only 21 sutures and if there was any additional sutures for 22 traction. 23 Q. Okay. 24 A. I mean some of it is likely to be</p>

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<p style="text-align: right;">Page 98</p> <p>1 the sutures. If it is the only sutures, if there was</p> <p>2 an additional suture, I cannot say.</p> <p>3 Q. And those sutures penetrated the</p> <p>4 muscle and the fascia?</p> <p>5 A. So second suture was on the right</p> <p>6 side of the fascia.</p> <p>7 Q. Uhm-hmm.</p> <p>8 A. Does not say that it penetrated.</p> <p>9 Q. And the first suture, which was the</p> <p>10 first sentence I read when we got on to this, it says,</p> <p>11 "A permanent suture was palpated on the left side of</p> <p>12 the fascia penetrating the muscle and the fascia." Do</p> <p>13 you see that?</p> <p>14 A. Yes, I do.</p> <p>15 Q. Okay. Did you consider the removal</p> <p>16 of these sutures and their placement through fascia and</p> <p>17 muscle when coming to your clinico-pathologic</p> <p>18 correlation regarding pain in this case?</p> <p>19 A. So if we go through the records,</p> <p>20 July, 2005, pain in the mesh area. Then November 2005</p> <p>21 pain in the mesh area. Then again, pain is associated</p> <p>22 with the mesh itself in October 2007, residual pain on</p> <p>23 the anterior side where she had the mesh implant.</p> <p>24 Q. October 2007 you would agree she</p>	<p style="text-align: right;">Page 100</p> <p>1 A. Well, I can see that, first of all,</p> <p>2 the clinical descriptions are connecting pain with the</p> <p>3 mesh itself, the mesh is being taken out, and initial</p> <p>4 excision of the mesh in the middle portion alleviated</p> <p>5 the symptoms or changed the pattern of symptoms.</p> <p>6 Again, at that time sutures were not removed, only the</p> <p>7 mesh was removed. And there was a change in pain.</p> <p>8 And when I examined the mesh</p> <p>9 microscopically, it provides much larger volume of the</p> <p>10 foreign material. The extent of tissue damage is much</p> <p>11 larger than what we see with the sutures, creates</p> <p>12 larger scar plate that attaches to larger area of</p> <p>13 tissues on its way.</p> <p>14 Q. Is it your opinion that</p> <p>15 Dr. Zimmerman, when he was completing his differential</p> <p>16 diagnosis, settled on the mesh itself and not the</p> <p>17 suture?</p> <p>18 A. The initial excision wasn't</p> <p>19 anywhere close to the sutures. The initial excision</p> <p>20 was in the mid-portion.</p> <p>21 Q. When coming to your -- or when</p> <p>22 undertaking your clinical pathologic correlation in</p> <p>23 this case, did you consider what role, if any,</p> <p>24 Ms. Stubblefield's use of pain medications and</p>
<p style="text-align: right;">Page 99</p> <p>1 still had the sutures that were removed two years</p> <p>2 later?</p> <p>3 A. Yes, but the description of the</p> <p>4 clinician is that, in relation to the mesh not to the</p> <p>5 sutures.</p> <p>6 Q. And would the sutures that were</p> <p>7 implanted as tensioning sutures necessarily be</p> <p>8 associated with the same area as the mesh?</p> <p>9 A. They are somewhat away. Again, I'm</p> <p>10 not urogynecologist and I'm not explanting surgeon to</p> <p>11 tell exactly where they were. Volume-wise the suture</p> <p>12 is much smaller in terms of the mesh. Just give me one</p> <p>13 second.</p> <p>14 So after the mesh excision, the midline</p> <p>15 pain went away. Again that specific pain in the</p> <p>16 middle where only the mesh was, no sutures went away.</p> <p>17 Q. Which record are you reading from?</p> <p>18 A. March 2011.</p> <p>19 Q. So the tensioning sutures were not</p> <p>20 in the midline?</p> <p>21 A. No.</p> <p>22 Q. So in this case, did you rule out</p> <p>23 the sutures as the -- as a cause of pelvic or vaginal</p> <p>24 pain for Ms. Stubblefield?</p>	<p style="text-align: right;">Page 101</p> <p>1 narcotics played on her pain symptoms?</p> <p>2 A. No. This would be a clinical</p> <p>3 question.</p> <p>4 Q. So you didn't consider that in</p> <p>5 September 2011, Ms. Stubblefield had a narcotics</p> <p>6 overdose resulting in detoxification where she realized</p> <p>7 she did not need the narcotic medications because she</p> <p>8 really did not experience any pain at all despite not</p> <p>9 being on any pain medications at all for four days and</p> <p>10 she realized she can live without pain medications?</p> <p>11 MR. ZIMMERMAN: Objections. Already</p> <p>12 asked and answered. Answer if you can.</p> <p>13 THE DEPONENT: It's beyond my scope.</p> <p>14 It's a clinical information.</p> <p>15 BY MR. SNOWDEN:</p> <p>16 Q. Go off the record for just a</p> <p>17 moment.</p> <p>18 -- OFF-THE-RECORD DISCUSSION --</p> <p>19 BY MR. SNOWDEN:</p> <p>20 Q. Dr. Iakovlev, would you agree that</p> <p>21 nerve entrapment can lead to numbness?</p> <p>22 A. It can.</p> <p>23 Q. Okay. I'll reserve the remainder</p> <p>24 of my time. Thank you.</p>

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<p>1 EXAMINATION BY MR. ZIMMERMAN:</p> <p>2 Q. Good evening, Doctor.</p> <p>3 A. Good evening.</p> <p>4 Q. I just have a few questions for</p> <p>5 you. I am going to introduce myself for the record.</p> <p>6 My name is Christopher Zimmerman and I'm here on behalf</p> <p>7 of the plaintiff. And I just have a couple questions.</p> <p>8 Doctor, it's true that you reached</p> <p>9 several opinions in this case, correct?</p> <p>10 A. Yes.</p> <p>11 Q. And those opinions are in summary</p> <p>12 form described in the expert report marked as Exhibit</p> <p>13 1?</p> <p>14 A. Yes.</p> <p>15 Q. And did you reach those opinions</p> <p>16 based on your education, skill, and expertise?</p> <p>17 A. Yes.</p> <p>18 Q. And do you hold those opinions to a</p> <p>19 reasonable degree of medical certainty?</p> <p>20 A. Yes, I do.</p> <p>21 Q. And I know you were asked over the</p> <p>22 last three hours many questions regarding</p> <p>23 Ms. Stubblefield. Have any of the questions posed to</p> <p>24 you today or any of the answers you have given changed</p>	<p>1 REPORTER'S CERTIFICATE</p> <p>2 I, TERRY WOOD, RPR, CSR, Certified</p> <p>3 Shorthand Reporter, certify;</p> <p>4 That the foregoing proceedings were</p> <p>5 taken before me at the time and place therein set</p> <p>6 forth, at which time the witness was put under oath by</p> <p>7 me;</p> <p>8 That the testimony of the witness and</p> <p>9 all objections made at the time of the examination were</p> <p>10 recorded stenographically by me and were thereafter</p> <p>11 transcribed;</p> <p>12 That the foregoing is a true and correct</p> <p>13 transcript of my shorthand notes so taken.</p> <p>14</p> <p>15</p> <p>16</p> <p>17 PER: TERRY WOOD, RPR, CSR</p> <p>18 REAL-TIME REPORTER</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 any of the opinions that you have already expressed in</p> <p>2 your report?</p> <p>3 A. No.</p> <p>4 MR. ZIMMERMAN: Those are all the</p> <p>5 questions. I have at this point.</p> <p>6 BY MR. ZIMMERMAN:</p> <p>7 Q. Dr. Iakovlev, thank you, and I hope</p> <p>8 this process of 35 depositions wasn't too painful for</p> <p>9 you.</p> <p>10 -- Whereupon the deposition concluded at 11:30 p.m.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 DEPOSITION ERRATA SHEET</p> <p>2 Case Caption: IN RE: ETHICON, INC., PELVIC REPAIR</p> <p>3 SYSTEM PRODUCTS LIABILITY LITIGATION</p> <p>4</p> <p>5 DECLARATION UNDER PENALTY OF PERJURY</p> <p>6 I declare under penalty of perjury that I have read</p> <p>7 the entire transcript of my deposition taken</p> <p>8 in the captioned matter or the same has been</p> <p>9 read to me, and the same is true and</p> <p>10 accurate, save and except for changes and/or</p> <p>11 corrections, if any, as indicated by me on</p> <p>12 the DEPOSITION ERRATA SHEET hereof, with the</p> <p>13 understanding that I offer these changes as</p> <p>14 if still under oath.</p> <p>15</p> <p>16 Signed on the _____ day of _____, 2016.</p> <p>17</p> <p>18 _____.</p> <p>19</p> <p>20 VLADIMIR IAKOVLEV, M.D.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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1            DEPOSITION ERRATA SHEET 2 3 4        Page No. _____ Line No. _____ Change to: _____ 5        _____ 6        Reason for change: _____ 7        Page No. _____ Line No. _____ Change to: _____ 8        _____ 9        Reason for change: _____ 10       Page No. _____ Line No. _____ Change to: _____ 11       _____ 12       Reason for change: _____ 13       Page No. _____ Line No. _____ Change to: _____ 14       _____ 15       Reason for change: _____ 16       Page No. _____ Line No. _____ Change to: _____ 17       _____ 18       Reason for change: _____ 19       Page No. _____ Line No. _____ Change to: _____ 20       _____ 21       Reason for change: _____ 22       Page No. _____ Line No. _____ Change to: _____ 23 24       SIGNATURE: _____ DATE: _____	